

US3622116 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:10:42

All time stamps listed in this document are displayed in GMT

US3622116

Form: Participant Creation

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

[Participant ID](#)

US3622116

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

US3622116

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Sep 2020 16:25:33

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Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Sep 2020 16:25:33

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

Condition	DIVERTICULITIS
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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

Condition	ABDOMINAL HERNIA
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	16 MAR 2021
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2021
Stop Year (derived)	2021

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:28 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:28
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	153 lb
BMI (<i>xxx.x</i>)	25.51377 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Sep 2020 16:25:33

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

CONSTRUCTION

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Sep 2020 16:25:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110029

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:28
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:45
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Sep 2020 16:25:33

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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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 11:15

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

31 AUG 2020 09:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	31 AUG 2020 09:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:25:33

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

31 AUG 2020 12:03

PC Open Date & Time

31 AUG 2020 11:35

PC Close Date & Time

31 AUG 2020 14:05

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp	31 AUG 2020 20:06
PC Open Date & Time	31 AUG 2020 15:00
PC Close Date & Time	01 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

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

01 SEP 2020 20:47

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:08

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

03 SEP 2020 20:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

04 SEP 2020 20:54

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

05 SEP 2020 21:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

97.6 °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

07 SEP 2020 09:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

31 AUG 2020 12:05

PC Open Date & Time

31 AUG 2020 11:35

PC Close Date & Time

31 AUG 2020 14:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 15:00

PC Close Date & Time

01 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

01 SEP 2020 20:47

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:09

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

05 SEP 2020 21:48

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

07 SEP 2020 09:59

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:07
PC Open Date & Time	31 AUG 2020 11:35
PC Close Date & Time	31 AUG 2020 14:05

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 20:08
PC Open Date & Time	31 AUG 2020 15:00
PC Close Date & Time	01 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:48
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:09
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:56
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:49
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 09:59
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3622116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 12:54:10

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:54:10

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 12:54:10

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:54:10

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

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)	28 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:07
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:30

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

What was the frequency of the study treatment dosing? ONCE

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

US3622116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

28 SEP 2020 10:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:14	28 SEP 2020 10:14
Nasopharyngeal Swab 2	No		

US3622116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

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 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °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	28 SEP 2020 18:12
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

96.3 °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

29 SEP 2020 19:51

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:26

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

97.6 °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

01 OCT 2020 21:19

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 20:19

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 20:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 20:26

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

28 SEP 2020 18:12

PC Open Date & Time

28 SEP 2020 15:15

PC Close Date & Time

29 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

29 SEP 2020 19:51

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

30 SEP 2020 21:27

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

01 OCT 2020 21:19

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

02 OCT 2020 20:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

03 OCT 2020 20:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

04 OCT 2020 20:26

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 11:50

PC Close Date & Time

28 SEP 2020 14:20

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 18:12
PC Open Date & Time	28 SEP 2020 15:15
PC Close Date & Time	29 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:52
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:27
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 21:20
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 20:20
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:50
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

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 ☒

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:26
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3622116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 17:56:56

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 17:56:56

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 19:55:18

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 19:55:18

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 14:50:05

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 14:50:05

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 16:21:55

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 16:21:55

Generated On: 10 Jun 2021 09:10:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 09:46
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 16:21:55

Generated On: 10 Jun 2021 09:10:42

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.

US3622116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 16:21:55

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

26 OCT 2020 09:50

US3622116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:21:55

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 05:47:49

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 06:46:58

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 19:41:38

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 06:52:34

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 00:06:14
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 19:25:35

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 18:49:15

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 08:13:51

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 12:28:04

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 07:07:11

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 06:29:19

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 20:20:40

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 17:08:49

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 06:42:03

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 19:58:59

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 06:56:12

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 11:57:03

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 15:56:13

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 06:39:09

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 06:12:57

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 06:57:34

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 20:50:55

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 18:40:37

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 07:55:51

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 06:39:55

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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°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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Patient Cloud Open Date & Time	14 JUL 2021 00:01
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Patient Cloud Close Date & Time	18 JUL 2021 23:59
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US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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="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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Patient Cloud Open Date & Time	22 DEC 2021 00:01
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Patient Cloud Close Date & Time	26 DEC 2021 23:59
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US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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°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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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="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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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°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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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="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"/>

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3622116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:10:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:28:35

US3622116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:02:54

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:02:54

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:02:54

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:02:54

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:53:55

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:53:55

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 11:16
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

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.

US3622116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

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

Collection date (dd MMM yyyy)	30 MAR 2021
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Collection time (00:00-23:59)	11:35 (24 HR)
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Collection date and time (derived)	30 MAR 2021 11:35
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US3622116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622116

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:10:42

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"/>

US3622116

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:10:42

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622116

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

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

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

Visit date (dd MMM yyyy)	19 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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US3622116

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:10:55

Generated On: 10 Jun 2021 09:10:42

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3622116

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Height	65 in
Weight	167 lb
BMI (xxx.x)	27.84836

US3622116

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Height	65 in
Weight	167 lb
BMI (xxx.x)	27.84836
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)	19 JAN 2021
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 12:48
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Height	65 in
Weight	167 lb
BMI (xxx.x)	27.84836
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)	19 JAN 2021
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:09
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

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

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

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.

US3622116

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

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 13:36 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 13:36

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

US3622116

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	13:05 (24 HR)
Collection date and time (derived)	19 JAN 2021 13:05

US3622116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	13:10
Collection Date and Time (derived)	19 JAN 2021 13:10

US3622116

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

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:06:20

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

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)	16 FEB 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 10:34
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

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)	16 FEB 2021
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 11:28
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	103 mmHg
Diastolic Blood Pressure units	MMHG

US3622116

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

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.

US3622116

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 10:56

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

US3622116

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:09:39

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:53:55

Generated On: 10 Jun 2021 09:10:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622116

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:53:55

Generated On: 10 Jun 2021 09:10:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622116

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:09:25

Generated On: 10 Jun 2021 09:10:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 20:09:25

Generated On: 10 Jun 2021 09:10:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:47 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 11:47
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	99 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622116

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:09:25

Generated On: 10 Jun 2021 09:10:42

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.

US3622116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:09:25

Generated On: 10 Jun 2021 09:10:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	23 MAR 2021 12:00

US3622116

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Oct 2020 12:06:12

Generated On: 10 Jun 2021 09:10:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID

Adverse event

TIRED FEELING

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)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID

Adverse event

BILATERAL UPPER EXTREMITY
MUSCLE ACHES

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)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

345 of 2595

EAB) (1725)

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	
Adverse event	INSOMNIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	USA-US085-2020-MRNA-1273-P30 1000003
Adverse event	VOMITING
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)	29 NOV 2020
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)	3 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	2 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.

UPDATE: PATIENT PRESENTED TO THE ER ON 12/01/2020 WITH RIGHT LOWER QUADRANT ABDOMINAL PAIN THAT WAS PRESENT X 2 DAYS. IN ADDITION, HE REPORTED SEVERAL EPISODES OF VOMITING, AND LOSS OF CONSCIOUSNESS. HE UNDERWENT A CT SCAN OF THE ABDOMEN AND PELVIS W/VO CONTRAST WHICH REVEALED MULTIPLE AREAS OF ATTENUATION CONSISTENT WITH LIVER CYSTS. CHEST X-RAY WHICH WAS NORMAL AND AN US OF THE LIVER WHICH REVEALED MULTIPLE CYSTS WITH THE LARGEST MEASURING 1.8CM. LABS REVEALED TOTAL BILIRUBIN WAS ABOVE NORMAL LIMITS AT 1.40 MG/DL. HE WAS ADMITTED FOR FURTHER EVALUATION. THE PATIENT LEFT THE HOSPITAL AMA ON 12/02/2020.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	USA-US085-2020-MRNA-1273-P30 1000003
Adverse event	RIGHT LOWER QUADRANT ABDOMINAL 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)	29 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	2 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.

UPDATE: PATIENT PRESENTED TO THE ER ON 12/01/2020 WITH RIGHT LOWER QUADRANT ABDOMINAL PAIN THAT WAS PRESENT X 2 DAYS. IN ADDITION, HE REPORTED SEVERAL EPISODES OF VOMITING, AND LOSS OF CONSCIOUSNESS. HE UNDERWENT A CT SCAN OF THE ABDOMEN AND PELVIS W/NO CONTRAST WHICH REVEALED MULTIPLE AREAS OF ATTENUATION CONSISTENT WITH LIVER CYSTS. CHEST X-RAY WHICH WAS NORMAL AND AN US OF THE LIVER WHICH REVEALED MULTIPLE CYSTS WITH THE LARGEST MEASURING 1.8CM. LABS REVEALED TOTAL BILIRUBIN WAS ABOVE NORMAL LIMITS AT 1.40 MG/DL. HE WAS ADMITTED FOR FURTHER EVALUATION. THE PATIENT LEFT THE HOSPITAL AMA ON 12/02/2020.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	USA-US085-2020-MRNA-1273-P30 1000003
Adverse event	LOSS OF CONSCIOUSNESS
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)	29 NOV 2020
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)	29 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	2 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

PARTICIPANT CALLED TODAY
TO REPORT THAT HE HAD
BEEN HOSPITALIZED FROM
NOVEMBER 29TH TO
DECEMBER 2ND, 2020, DUE TO 6
EPISODES OF VOMITING AND
LOSS OF CONSCIOUSNESS.

UPDATE: PATIENT PRESENTED
TO THE ER ON 12/01/2020 WITH
RIGHT LOWER QUADRANT
ABDOMINAL PAIN THAT WAS
PRESENT X 2 DAYS. IN
ADDITION, HE REPORTED
SEVERAL EPISODES OF
VOMITING, AND LOSS OF
CONSCIOUSNESS. HE
UNDERWENT A CT SCAN OF
THE ABDOMEN AND PELVIS
W/WO CONTRAST WHICH
REVEALED MULTIPLE AREAS
OF ATTENUATION CONSISTENT
WITH LIVER CYSTS. CHEST
X-RAY WHICH WAS NORMAL
AND AN US OF THE LIVER
WHICH REVEALED MULTIPLE
CYSTS WITH THE LARGEST
MEASURING 1.8CM. LABS
REVEALED TOTAL BILIRUBIN
WAS ABOVE NORMAL LIMITS
AT 1.40 MG/DL. HE WAS
ADMITTED FOR FURTHER
EVALUATION. THE PATIENT
LEFT THE HOSPITAL AMA ON
12/02/2020.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	USA-US085-2020-MRNA-1273-P30 1000003
Adverse event	NAUSEA
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)	29 NOV 2020
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)	3 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	2 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.

UPDATE: PATIENT PRESENTED TO THE ER ON 12/01/2020 WITH RIGHT LOWER QUADRANT ABDOMINAL PAIN THAT WAS PRESENT X 2 DAYS. IN ADDITION, HE REPORTED SEVERAL EPISODES OF VOMITING, AND LOSS OF CONSCIOUSNESS. HE UNDERWENT A CT SCAN OF THE ABDOMEN AND PELVIS W/NO CONTRAST WHICH REVEALED MULTIPLE AREAS OF ATTENUATION CONSISTENT WITH LIVER CYSTS. CHEST X-RAY WHICH WAS NORMAL AND AN US OF THE LIVER WHICH REVEALED MULTIPLE CYSTS WITH THE LARGEST MEASURING 1.8CM. LABS REVEALED TOTAL BILIRUBIN WAS ABOVE NORMAL LIMITS AT 1.40 MG/DL. HE WAS ADMITTED FOR FURTHER EVALUATION. THE PATIENT LEFT THE HOSPITAL AMA ON 12/02/2020.

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID	
Adverse event	GAS
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)	29 NOV 2020
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)	3 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID

Adverse event

CONSTIPATION

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)

29 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

AEID

Adverse event

LIVER CYST

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)

29 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 16:05:48

Generated On: 10 Jun 2021 09:10:42

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 16:05:48

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AEID	
Adverse event	GERD
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)	1 DEC 2020
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)	1 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

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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)	_____

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Sep 2020 16:25:33

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1980
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication OMEGA 3

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1980
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT VITAMIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT VITAMIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:54:29

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Name of Medication LIVALO

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)		15 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)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:54:29

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Name of Medication SEASONAL FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:54:29

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	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)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:54:29

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Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN (RIGHT LOWER QUADRANT)

Dose per administration 4

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:54:29

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	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)		1 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA, VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)		1 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)	1 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 1 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication IOPAMIDOL

Prophylaxis Yes ☐
No ☒

Indication RADIOPAQUE CONTRAST
AGENT

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 ☐

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US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)		1 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 DEC 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"/>

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2595

EAB) (1725)

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

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

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR

Dose per administration 325/5

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)

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US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)	16 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)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:54:29

Generated On: 10 Jun 2021 09:10:42

	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)	16 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) 22 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"/>

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 14:02:26

Generated On: 10 Jun 2021 09:10:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 01 Apr 2021 18:13:59

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 DEC 2020	CHEST X-RAY	Diagnostic	
1 DEC 2020	CT ABDOMEN AND PELVIS WITH AND WITHOUT CONTRAST	Diagnostic	
1 DEC 2020	LIVER ULTRASOUND	Diagnostic	
22 FEB 2021	COLONOSCOPY	Diagnostic	
16 MAR 2021	ABDOMINAL HERNIA REPAIR	Medical History	

US3622116

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:10:42

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 ☐

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/DEC/2020 15:07
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/DEC/2020 13:18
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/DEC/2020 19:12
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/DEC/2020 12:51
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	27/JAN/2021 11:41
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/FEB/2021 13:50
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/FEB/2021 10:46
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	29/APR/2021 12:31
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

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 30 Apr 2021 16:05:49

Generated On: 10 Jun 2021 09:10:42

SAEID	USA-US085-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	29/APR/2021 16:09
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

US3622116 (Prod: University of Miami)

US3622116

Form: Participant Creation

Generated On: 10 Jun 2021 09:10:42

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'US3622116'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:35:21

US3622116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:18

US3622116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:35:22

US3622116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:18

US3622116

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'SCRN'	System	31 Aug 2020 15:18:18

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:35:23

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '55'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'YEARS'	System	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '55'	System	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:10:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:55:47

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'Aug 2020'	System	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '2020'	System	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:31

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:35:22

US3622116

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:10:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'I'	System	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:10:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:40:37

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User coded data point as SOC: Investigations, HLGt: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 20:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:42:49
Data point term sent to Coder	System	09 Sep 2020 20:42:02
User entered 'high cholesterol'	(b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'Jan 2019'	System	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '2019'	System	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	09 Sep 2020 20:41:10

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 19:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:27:49
Data point term sent to Coder	System	26 Jan 2021 19:27:16
User entered 'diverticulitis'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'I'	Junlin Long	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '0'	Junlin Long	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered empty.	System	26 Jan 2021 19:26:19

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Mar 2021 13:29:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:29:23
Data point term sent to Coder	System	31 Mar 2021 13:28:25
User entered 'abdominal hernia'	(b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'Jun 2020'	System	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '2020'	System	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'Mar 2021'	System	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '2021'	System	31 Mar 2021 13:27:57

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '09:28'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '31 Aug 2020 09:28'	System	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '65' in	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09
DataPoint set to visible.	System	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '153' lb	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09
DataPoint set to visible.	System	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '25.51377'	System	09 Sep 2020 20:42:09
DataPoint set to visible.	System	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'kg/m2'	System	09 Sep 2020 20:42:09
DataPoint set to visible.	System	31 Aug 2020 15:18:35

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'bpm'	System	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'breaths/min'	System	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	09 Sep 2020 20:42:09

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19

US3622116

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19

US3622116

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:27

US3622116

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:42:27

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'construction'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:10:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:43:48

US3622116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:49

US3622116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:49

US3622116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:18:49

US3622116

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'VISIT1'	System	31 Aug 2020 15:18:49

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:39:36

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '110029'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:39:36

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 14:39:36

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 14:09:15
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 20:49:33
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 20:49:13
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:13:45

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:49:13

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:49:13

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:49:13

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:49:13

US3622116

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:10:42

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long	30 Sep 2020 16:31:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:50:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:41:59

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '09:28'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '31 Aug 2020 09:28'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '71'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'bpm'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'breaths/min'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '120'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '89'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '11:45'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '31 Aug 2020 11:45'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '61'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'bpm'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '18'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'breaths/min'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '120'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '83'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	09 Sep 2020 20:53:24

US3622116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:02

US3622116

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:02

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '11:15'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '31 Aug 2020 11:15'	System	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'ONCE'	System	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:19:08

US3622116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:49

US3622116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:49

US3622116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '09:35'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:54:49

US3622116

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '31 Aug 2020 09:35'	System	09 Sep 2020 20:54:49

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '09:40'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '31 Aug 2020 09:40'	System	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered empty.	System	09 Sep 2020 20:55:21

US3622116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 12:13:45

US3622116

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'I'	System	12 Sep 2020 12:13:45

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T11:59:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b0f92764-e552-4c4a-b76d-c4da49b9fb52'	System	31 Aug 2020 16:04:00
User entered 'Yes (Y)'	System	31 Aug 2020 16:04:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:01:39', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b0f92764-e552-4c4a-b76d-c4da49b9fb52' User entered '97.6'	System	31 Aug 2020 16:04:00
	System	31 Aug 2020 16:04:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:01:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b0f92764-e552-4c4a-b76d-c4da49b9fb52'	System	31 Aug 2020 16:04:00
User entered 'No (N)'	System	31 Aug 2020 16:04:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:03:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b0f92764-e552-4c4a-b76d-c4da49b9fb52'	System	31 Aug 2020 16:04:00
User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:04:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:05:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '218cf761-c74d-41b2-a713-02fe045c5207' User entered 'Yes (Y)'	System	02 Sep 2020 00:46:38
	System	02 Sep 2020 00:46:38

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:06:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '218cf761-c74d-41b2-a713-02fe045c5207' User entered '97.8'	System	02 Sep 2020 00:46:38
	System	02 Sep 2020 00:46:38

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:06:17', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '218cf761-c74d-41b2-a713-02fe045c5207'	System	02 Sep 2020 00:46:38
User entered 'No (N)'	System	02 Sep 2020 00:46:38

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:06:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '218cf761-c74d-41b2-a713-02fe045c5207'	System	02 Sep 2020 00:46:38
User entered '31 Aug 2020 20:06'	System	02 Sep 2020 00:46:38

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 2'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:46:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ad9d6f7c-b74c-4c35-a124-3025713f58ab' User entered 'Yes (Y)'	System	02 Sep 2020 00:47:08
	System	02 Sep 2020 00:47:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:46:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ad9d6f7c-b74c-4c35-a124-3025713f58ab' User entered '96.8'	System	02 Sep 2020 00:47:08
	System	02 Sep 2020 00:47:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:46:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ad9d6f7c-b74c-4c35-a124-3025713f58ab' User entered 'No (N)'	System	02 Sep 2020 00:47:08
	System	02 Sep 2020 00:47:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ad9d6f7c-b74c-4c35-a124-3025713f58ab' User entered '01 Sep 2020 20:47'	System	02 Sep 2020 00:47:08
	System	02 Sep 2020 00:47:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 3'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:07:57', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a399c3a5-1a2f-4f70-8e05-d3dd894de3e3'	System	03 Sep 2020 00:08:39
User entered 'Yes (Y)'	System	03 Sep 2020 00:08:39

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:08', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a399c3a5-1a2f-4f70-8e05-d3dd894de3e3' User entered '96.7'	System	03 Sep 2020 00:08:39
	System	03 Sep 2020 00:08:39

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a399c3a5-1a2f-4f70-8e05-d3dd894de3e3'	System	03 Sep 2020 00:08:39
User entered 'No (N)'	System	03 Sep 2020 00:08:39

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a399c3a5-1a2f-4f70-8e05-d3dd894de3e3'	System	03 Sep 2020 00:08:39
User entered '02 Sep 2020 20:08'	System	03 Sep 2020 00:08:39

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 4'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:37:32', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '805c1037-e355-42f7-9215-a648bea42e56'	System	04 Sep 2020 00:38:00
User entered 'Yes (Y)'	System	04 Sep 2020 00:38:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:37:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '805c1037-e355-42f7-9215-a648bea42e56' User entered '96.5'	System	04 Sep 2020 00:38:00
	System	04 Sep 2020 00:38:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:37:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '805c1037-e355-42f7-9215-a648bea42e56'	System	04 Sep 2020 00:38:00
User entered 'No (N)'	System	04 Sep 2020 00:38:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:37:57', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '805c1037-e355-42f7-9215-a648bea42e56'	System	04 Sep 2020 00:38:00
User entered '03 Sep 2020 20:37'	System	04 Sep 2020 00:38:00

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 5'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:54:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '0ec111b8-6730-496b-bbbe-cddb85ead6b9' User entered 'Yes (Y)'	System	05 Sep 2020 00:54:54
	System	05 Sep 2020 00:54:54

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:54:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '0ec111b8-6730-496b-bbbe-cddb85ead6b9' User entered '97.6'	System	05 Sep 2020 00:54:54
	System	05 Sep 2020 00:54:54

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:54:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '0ec111b8-6730-496b-bbbe-cddb85ead6b9' User entered 'No (N)'	System	05 Sep 2020 00:54:54
	System	05 Sep 2020 00:54:54

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:54:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '0ec111b8-6730-496b-bbbe-cddb85ead6b9' User entered '04 Sep 2020 20:54'	System	05 Sep 2020 00:54:54
	System	05 Sep 2020 00:54:54

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 6'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6cb9dd62-b5e5-41aa-a286-fb37124510eb' User entered 'Yes (Y)'	System	06 Sep 2020 01:48:26
	System	06 Sep 2020 01:48:26

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:11', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6cb9dd62-b5e5-41aa-a286-fb37124510eb' User entered '97.8'	System	06 Sep 2020 01:48:26
	System	06 Sep 2020 01:48:26

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6cb9dd62-b5e5-41aa-a286-fb37124510eb' User entered 'No (N)'	System	06 Sep 2020 01:48:26
	System	06 Sep 2020 01:48:26

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:24', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6cb9dd62-b5e5-41aa-a286-fb37124510eb' User entered '05 Sep 2020 21:48'	System	06 Sep 2020 01:48:26
	System	06 Sep 2020 01:48:26

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 7'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:58:36', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f95d6a42-f17d-45ca-a0e0-25dcb3255979' User entered 'Yes (Y)'	System	07 Sep 2020 13:58:56
	System	07 Sep 2020 13:58:56

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:58:43', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f95d6a42-f17d-45ca-a0e0-25dcb3255979' User entered '97.6'	System	07 Sep 2020 13:58:56
	System	07 Sep 2020 13:58:56

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:58:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f95d6a42-f17d-45ca-a0e0-25dcb3255979' User entered 'No (N)'	System	07 Sep 2020 13:58:56
	System	07 Sep 2020 13:58:56

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:58:53', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f95d6a42-f17d-45ca-a0e0-25dcb3255979' User entered '07 Sep 2020 09:58'	System	07 Sep 2020 13:58:56
	System	07 Sep 2020 13:58:56

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:03:43', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5153385c-53f6-4e87-a061-1979c7bd0de4' User entered 'None (1)'	System	31 Aug 2020 16:09:02
	System	31 Aug 2020 16:09:02

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:04:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5153385c-53f6-4e87-a061-1979c7bd0de4' User entered 'No (N)'	System	31 Aug 2020 16:09:02
	System	31 Aug 2020 16:09:02

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:04:39', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5153385c-53f6-4e87-a061-1979c7bd0de4' User entered 'No (N)'	System	31 Aug 2020 16:09:02
	System	31 Aug 2020 16:09:02

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:04:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5153385c-53f6-4e87-a061-1979c7bd0de4' User entered 'None (1)'	System	31 Aug 2020 16:09:02
	System	31 Aug 2020 16:09:02

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:05:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5153385c-53f6-4e87-a061-1979c7bd0de4' User entered '31 Aug 2020 12:05'	System	31 Aug 2020 16:09:02
	System	31 Aug 2020 16:09:02

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:07:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ac88db28-bacd-44cc-a9a8-e444305ce4d8'	System	02 Sep 2020 00:46:41
User entered 'None (1)'	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:07:38', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ac88db28-bacd-44cc-a9a8-e444305ce4d8' User entered 'No (N)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:07:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ac88db28-bacd-44cc-a9a8-e444305ce4d8' User entered 'No (N)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:07:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ac88db28-bacd-44cc-a9a8-e444305ce4d8' User entered 'None (1)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:07:59', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'ac88db28-bacd-44cc-a9a8-e444305ce4d8'	System	02 Sep 2020 00:46:41
User entered '31 Aug 2020 20:07'	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 2'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f2ac40cc-7fb1-4dde-a0cd-56fd45326f0b'	System	02 Sep 2020 00:47:54
User entered 'None (1)'	System	02 Sep 2020 00:47:54

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:22', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f2ac40cc-7fb1-4dde-a0cd-56fd45326f0b'	System	02 Sep 2020 00:47:54
User entered 'No (N)'	System	02 Sep 2020 00:47:54

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:28', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f2ac40cc-7fb1-4dde-a0cd-56fd45326f0b' User entered 'No (N)'	System	02 Sep 2020 00:47:54
	System	02 Sep 2020 00:47:54

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:35', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f2ac40cc-7fb1-4dde-a0cd-56fd45326f0b' User entered 'None (1)'	System	02 Sep 2020 00:47:54
	System	02 Sep 2020 00:47:54

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:47:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f2ac40cc-7fb1-4dde-a0cd-56fd45326f0b' User entered '01 Sep 2020 20:47'	System	02 Sep 2020 00:47:54
	System	02 Sep 2020 00:47:54

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 3'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b128cd2a-48c2-4a34-a3d9-b9d68cd0cfd6'	System	03 Sep 2020 00:09:05
User entered 'None (1)'	System	03 Sep 2020 00:09:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b128cd2a-48c2-4a34-a3d9-b9d68cd0cfd6' User entered 'No (N)'	System	03 Sep 2020 00:09:05
	System	03 Sep 2020 00:09:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:53', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b128cd2a-48c2-4a34-a3d9-b9d68cd0cfd6' User entered 'No (N)'	System	03 Sep 2020 00:09:05
	System	03 Sep 2020 00:09:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:08:57', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b128cd2a-48c2-4a34-a3d9-b9d68cd0cfd6'	System	03 Sep 2020 00:09:05
User entered 'None (1)'	System	03 Sep 2020 00:09:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b128cd2a-48c2-4a34-a3d9-b9d68cd0cfd6'	System	03 Sep 2020 00:09:05
User entered '02 Sep 2020 20:09'	System	03 Sep 2020 00:09:05

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 4'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:03', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'afd9073c-d1f5-46d7-8fbd-c48ffb64d67f' User entered 'None (1)'	System	04 Sep 2020 00:38:30
	System	04 Sep 2020 00:38:30

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:08', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'afd9073c-d1f5-46d7-8fbd-c48ffb64d67f' User entered 'No (N)'	System	04 Sep 2020 00:38:30
	System	04 Sep 2020 00:38:30

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'afd9073c-d1f5-46d7-8fbd-c48ffb64d67f' User entered 'No (N)'	System	04 Sep 2020 00:38:30
	System	04 Sep 2020 00:38:30

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'afd9073c-d1f5-46d7-8fbd-c48ffb64d67f' User entered 'None (1)'	System	04 Sep 2020 00:38:30
	System	04 Sep 2020 00:38:30

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'afd9073c-d1f5-46d7-8fbd-c48ffb64d67f' User entered '03 Sep 2020 20:38'	System	04 Sep 2020 00:38:30
	System	04 Sep 2020 00:38:30

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 5'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:18', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '8e7d9fb4-d763-48be-b700-ce69665c5239'	System	05 Sep 2020 00:55:39
User entered 'None (1)'	System	05 Sep 2020 00:55:39

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '8e7d9fb4-d763-48be-b700-ce69665c5239' User entered 'No (N)'	System	05 Sep 2020 00:55:39
	System	05 Sep 2020 00:55:39

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:28', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '8e7d9fb4-d763-48be-b700-ce69665c5239'	System	05 Sep 2020 00:55:39
User entered 'No (N)'	System	05 Sep 2020 00:55:39

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:33', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '8e7d9fb4-d763-48be-b700-ce69665c5239'	System	05 Sep 2020 00:55:39
User entered 'None (1)'	System	05 Sep 2020 00:55:39

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '8e7d9fb4-d763-48be-b700-ce69665c5239'	System	05 Sep 2020 00:55:39
User entered '04 Sep 2020 20:55'	System	05 Sep 2020 00:55:39

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 6'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'e1381a3e-e25d-4b59-8b5c-5a62e1e4a83f' User entered 'None (1)'	System	06 Sep 2020 01:48:56
	System	06 Sep 2020 01:48:56

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:41', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'e1381a3e-e25d-4b59-8b5c-5a62e1e4a83f' User entered 'No (N)'	System	06 Sep 2020 01:48:56
	System	06 Sep 2020 01:48:56

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'e1381a3e-e25d-4b59-8b5c-5a62e1e4a83f' User entered 'No (N)'	System	06 Sep 2020 01:48:56
	System	06 Sep 2020 01:48:56

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'e1381a3e-e25d-4b59-8b5c-5a62e1e4a83f' User entered 'None (1)'	System	06 Sep 2020 01:48:56
	System	06 Sep 2020 01:48:56

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'e1381a3e-e25d-4b59-8b5c-5a62e1e4a83f' User entered '05 Sep 2020 21:48'	System	06 Sep 2020 01:48:56
	System	06 Sep 2020 01:48:56

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 7'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:58:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c524b1c-4983-445b-a028-48f676dd958f' User entered 'None (1)'	System	07 Sep 2020 13:59:27
	System	07 Sep 2020 13:59:27

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c524b1c-4983-445b-a028-48f676dd958f' User entered 'No (N)'	System	07 Sep 2020 13:59:27
	System	07 Sep 2020 13:59:27

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c524b1c-4983-445b-a028-48f676dd958f' User entered 'No (N)'	System	07 Sep 2020 13:59:27
	System	07 Sep 2020 13:59:27

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:21', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c524b1c-4983-445b-a028-48f676dd958f' User entered 'None (1)'	System	07 Sep 2020 13:59:27
	System	07 Sep 2020 13:59:27

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:25', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c524b1c-4983-445b-a028-48f676dd958f' User entered '07 Sep 2020 09:59'	System	07 Sep 2020 13:59:27
	System	07 Sep 2020 13:59:27

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:05:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77' User entered 'None (0)'	System	31 Aug 2020 16:09:46
	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:05:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77'	System	31 Aug 2020 16:09:46
User entered 'None (0)'	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:06:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77' User entered 'None (0)'	System	31 Aug 2020 16:09:46
	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:06:20', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77' User entered 'None (0)'	System	31 Aug 2020 16:09:46
	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:06:29', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77' User entered 'None (0)'	System	31 Aug 2020 16:09:46
	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:06:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77' User entered 'None (0)'	System	31 Aug 2020 16:09:46
	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:06:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77'	System	31 Aug 2020 16:09:46
User entered 'No (N)'	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T12:07:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '044dd6e9-3fc5-4a59-8575-9ad2ca1d6a77'	System	31 Aug 2020 16:09:46
User entered '31 Aug 2020 12:07'	System	31 Aug 2020 16:09:46

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 11:35'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 14:05'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:06', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:10', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:17', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:20', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'None (0)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:38', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c' User entered 'No (N)'	System	02 Sep 2020 00:46:41
	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-08-31T20:08:41', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '21744fb4-a5c4-425e-b242-d87cd738f62c'	System	02 Sep 2020 00:46:41
User entered '31 Aug 2020 20:08'	System	02 Sep 2020 00:46:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '31 Aug 2020 15:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 2'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:08', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:13', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:16', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:21', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:24', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'None (0)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:32', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered 'No (N)'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-01T20:48:38', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'b5698359-f382-4f61-beec-9b60060ac8e6' User entered '01 Sep 2020 20:48'	System	02 Sep 2020 00:48:41
	System	02 Sep 2020 00:48:41

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 3'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:10', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:13', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:16', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:20', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'None (0)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:33', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered 'No (N)'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-02T20:09:39', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9be55b6f-9207-4bf5-bc0a-f400d45c5bba' User entered '02 Sep 2020 20:09'	System	03 Sep 2020 00:09:42
	System	03 Sep 2020 00:09:42

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 4'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:31', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'None (0)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:38:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered 'No (N)'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-03T20:39:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'c45e751f-e8d2-4cee-8017-bfc16053f561' User entered '03 Sep 2020 20:39'	System	04 Sep 2020 00:39:03
	System	04 Sep 2020 00:39:03

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 5'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:51', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:54', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:55:57', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'None (0)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:56:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered 'No (N)'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-04T20:56:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd5c62bfd-b572-4b08-b757-275777b2fcff' User entered '04 Sep 2020 20:56'	System	05 Sep 2020 00:56:06
	System	05 Sep 2020 00:56:06

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 6'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:48:57', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:08', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:11', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'None (0)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered 'No (N)'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-05T21:49:22', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04a8459d-f0fa-403d-bf89-d8a4616957d7' User entered '05 Sep 2020 21:49'	System	06 Sep 2020 01:49:25
	System	06 Sep 2020 01:49:25

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 7'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:31', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'None (0)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466' User entered 'No (N)'	System	07 Sep 2020 14:00:04
	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-07T09:59:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2c14cee4-37ea-4102-acc8-287746f8b466'	System	07 Sep 2020 14:00:04
User entered '07 Sep 2020 09:59'	System	07 Sep 2020 14:00:04

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:19:08

US3622116

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:10:47

US3622116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:10:47

US3622116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:10:47

US3622116

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:10:47

US3622116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:10:59

US3622116

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	16 Sep 2020 17:10:59

US3622116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:11:11

US3622116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered '14 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 17:11:11

US3622116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 17:11:11

US3622116

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:11:11

US3622116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:11:20

US3622116

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	16 Sep 2020 17:11:20

US3622116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:51:42

US3622116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	28 Sep 2020 14:51:51
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Sep 2020 14:51:51
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:51:51
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Sep 2020 14:51:42
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 14:51:42

US3622116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:51:42

US3622116

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:51:42

US3622116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:51:59

US3622116

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	28 Sep 2020 14:51:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:34:10

US3622116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:34:10

US3622116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:34:10

US3622116

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'VISIT2'	System	28 Sep 2020 15:34:10

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '10:04'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '28 Sep 2020 10:04'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '98.4' F	Junlin Long (b) (4)	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Oral (Oral)'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '74'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'bpm'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '18'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'breaths/min'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '122'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '85'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '12:07'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '28 Sep 2020 12:07'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '97.5' F	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Oral (Oral)'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '69'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'bpm'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '18'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'breaths/min'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '122'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '88'	Junlin Long	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	30 Sep 2020 16:34:41

US3622116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:34:51

US3622116

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	Junlin Long	30 Sep 2020 16:34:51

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '11:30'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '28 Sep 2020 11:30'	System	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'ONCE'	System	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:33:59

US3622116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:35:04

US3622116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	Junlin Long	30 Sep 2020 16:35:04

US3622116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '10:20'	Junlin Long	30 Sep 2020 16:35:04

US3622116

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '28 Sep 2020 10:20'	System	30 Sep 2020 16:35:04

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '28 Sep 2020'	Junlin Long (b) (4)	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long (b) (4)	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '10:14'	Junlin Long	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '28 Sep 2020 10:14'	System	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered empty.	System	30 Sep 2020 16:35:20

US3622116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:35:25

US3622116

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '1'	System	30 Sep 2020 16:35:25

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:11:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '685619c5-3a07-4a1d-8833-a89b67dd91a3' User entered 'Yes (Y)'	System	28 Sep 2020 22:12:08
	System	28 Sep 2020 22:12:08

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:11:54', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '685619c5-3a07-4a1d-8833-a89b67dd91a3' User entered '97.5'	System	28 Sep 2020 22:12:08
	System	28 Sep 2020 22:12:08

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:11:59', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '685619c5-3a07-4a1d-8833-a89b67dd91a3'	System	28 Sep 2020 22:12:08
User entered 'No (N)'	System	28 Sep 2020 22:12:08

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:05', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '685619c5-3a07-4a1d-8833-a89b67dd91a3' User entered '28 Sep 2020 18:12'	System	28 Sep 2020 22:12:08
	System	28 Sep 2020 22:12:08

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 2'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:50:25', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2156e4b4-b892-4ea7-9d5c-92507dad9bb6' User entered 'Yes (Y)'	System	29 Sep 2020 23:51:17
	System	29 Sep 2020 23:51:17

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:06', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2156e4b4-b892-4ea7-9d5c-92507dad9bb6' User entered '96.3'	System	29 Sep 2020 23:51:17
	System	29 Sep 2020 23:51:17

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:09', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2156e4b4-b892-4ea7-9d5c-92507dad9bb6'	System	29 Sep 2020 23:51:17
User entered 'No (N)'	System	29 Sep 2020 23:51:17

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2156e4b4-b892-4ea7-9d5c-92507dad9bb6' User entered '29 Sep 2020 19:51'	System	29 Sep 2020 23:51:17
	System	29 Sep 2020 23:51:17

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 3'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:09', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a382141a-f2a1-45c0-8860-cdb09ad5a740' User entered 'Yes (Y)'	System	01 Oct 2020 01:26:30
	System	01 Oct 2020 01:26:30

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a382141a-f2a1-45c0-8860-cdb09ad5a740' User entered '98.2'	System	01 Oct 2020 01:26:30
	System	01 Oct 2020 01:26:30

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:18', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a382141a-f2a1-45c0-8860-cdb09ad5a740'	System	01 Oct 2020 01:26:30
User entered 'No (N)'	System	01 Oct 2020 01:26:30

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:25', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a382141a-f2a1-45c0-8860-cdb09ad5a740' User entered '30 Sep 2020 21:26'	System	01 Oct 2020 01:26:30
	System	01 Oct 2020 01:26:30

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 4'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:18:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2142b56c-9d65-42f5-888c-344f96d1aaea' User entered 'Yes (Y)'	System	02 Oct 2020 01:19:16
	System	02 Oct 2020 01:19:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:10', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2142b56c-9d65-42f5-888c-344f96d1aeea' User entered '97.6'	System	02 Oct 2020 01:19:16
	System	02 Oct 2020 01:19:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:18:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2142b56c-9d65-42f5-888c-344f96d1aaea' User entered 'No (N)'	System	02 Oct 2020 01:19:16
	System	02 Oct 2020 01:19:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2142b56c-9d65-42f5-888c-344f96d1aaea' User entered '01 Oct 2020 21:19'	System	02 Oct 2020 01:19:16
	System	02 Oct 2020 01:19:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 5'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd39ce74b-7b67-4147-a866-0592ae7323be' User entered 'Yes (Y)'	System	03 Oct 2020 00:19:52
	System	03 Oct 2020 00:19:52

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd39ce74b-7b67-4147-a866-0592ae7323be' User entered '96.5'	System	03 Oct 2020 00:19:52
	System	03 Oct 2020 00:19:52

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd39ce74b-7b67-4147-a866-0592ae7323be' User entered 'No (N)'	System	03 Oct 2020 00:19:52
	System	03 Oct 2020 00:19:52

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd39ce74b-7b67-4147-a866-0592ae7323be' User entered '02 Oct 2020 20:19'	System	03 Oct 2020 00:19:52
	System	03 Oct 2020 00:19:52

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 6'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04478615-5877-48e0-a456-ccd738851f16' User entered 'Yes (Y)'	System	04 Oct 2020 00:49:44
	System	04 Oct 2020 00:49:44

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:33', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04478615-5877-48e0-a456-ccd738851f16' User entered '97.0'	System	04 Oct 2020 00:49:44
	System	04 Oct 2020 00:49:44

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04478615-5877-48e0-a456-ccd738851f16'	System	04 Oct 2020 00:49:44
User entered 'No (N)'	System	04 Oct 2020 00:49:44

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '04478615-5877-48e0-a456-ccd738851f16' User entered '03 Oct 2020 20:49'	System	04 Oct 2020 00:49:44
	System	04 Oct 2020 00:49:44

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 7'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:25:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '07556881-4c63-427c-9a83-4f271b29892b' User entered 'Yes (Y)'	System	05 Oct 2020 00:26:16
	System	05 Oct 2020 00:26:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:03', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '07556881-4c63-427c-9a83-4f271b29892b' User entered '96.8'	System	05 Oct 2020 00:26:16
	System	05 Oct 2020 00:26:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:09', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '07556881-4c63-427c-9a83-4f271b29892b' User entered 'No (N)'	System	05 Oct 2020 00:26:16
	System	05 Oct 2020 00:26:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '07556881-4c63-427c-9a83-4f271b29892b' User entered '04 Oct 2020 20:26'	System	05 Oct 2020 00:26:16
	System	05 Oct 2020 00:26:16

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:13', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '23c41809-9270-4932-9d3f-779ca16dccfc'	System	28 Sep 2020 22:12:30
User entered 'None (1)'	System	28 Sep 2020 22:12:30

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:16', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '23c41809-9270-4932-9d3f-779ca16dccfc' User entered 'No (N)'	System	28 Sep 2020 22:12:30
	System	28 Sep 2020 22:12:30

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '23c41809-9270-4932-9d3f-779ca16dccfc' User entered 'No (N)'	System	28 Sep 2020 22:12:30
	System	28 Sep 2020 22:12:30

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '23c41809-9270-4932-9d3f-779ca16dccfc'	System	28 Sep 2020 22:12:30
User entered 'None (1)'	System	28 Sep 2020 22:12:30

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:27', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '23c41809-9270-4932-9d3f-779ca16dccfc' User entered '28 Sep 2020 18:12'	System	28 Sep 2020 22:12:30
	System	28 Sep 2020 22:12:30

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 2'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:20', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f69262c3-0ec9-40c9-8724-ba9299463bab' User entered 'None (1)'	System	29 Sep 2020 23:51:39
	System	29 Sep 2020 23:51:39

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:25', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f69262c3-0ec9-40c9-8724-ba9299463bab' User entered 'No (N)'	System	29 Sep 2020 23:51:39
	System	29 Sep 2020 23:51:39

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:29', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f69262c3-0ec9-40c9-8724-ba9299463bab' User entered 'No (N)'	System	29 Sep 2020 23:51:39
	System	29 Sep 2020 23:51:39

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:32', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f69262c3-0ec9-40c9-8724-ba9299463bab' User entered 'None (1)'	System	29 Sep 2020 23:51:39
	System	29 Sep 2020 23:51:39

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:35', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f69262c3-0ec9-40c9-8724-ba9299463bab' User entered '29 Sep 2020 19:51'	System	29 Sep 2020 23:51:39
	System	29 Sep 2020 23:51:39

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 3'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '767e4d29-efdb-422f-9307-57495a84c9a2'	System	01 Oct 2020 01:27:12
User entered 'None (1)'	System	01 Oct 2020 01:27:12

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:51', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '767e4d29-efdb-422f-9307-57495a84c9a2'	System	01 Oct 2020 01:27:12
User entered 'No (N)'	System	01 Oct 2020 01:27:12

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:26:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '767e4d29-efdb-422f-9307-57495a84c9a2'	System	01 Oct 2020 01:27:12
User entered 'No (N)'	System	01 Oct 2020 01:27:12

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:05', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '767e4d29-efdb-422f-9307-57495a84c9a2'	System	01 Oct 2020 01:27:12
User entered 'None (1)'	System	01 Oct 2020 01:27:12

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:11', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '767e4d29-efdb-422f-9307-57495a84c9a2'	System	01 Oct 2020 01:27:12
User entered '30 Sep 2020 21:27'	System	01 Oct 2020 01:27:12

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 4'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7621ffc3-8d00-4706-953f-60f38368f89a'	System	02 Oct 2020 01:19:37
User entered 'None (1)'	System	02 Oct 2020 01:19:37

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7621ffc3-8d00-4706-953f-60f38368f89a' User entered 'No (N)'	System	02 Oct 2020 01:19:37
	System	02 Oct 2020 01:19:37

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:27', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7621ffc3-8d00-4706-953f-60f38368f89a' User entered 'No (N)'	System	02 Oct 2020 01:19:37
	System	02 Oct 2020 01:19:37

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7621ffc3-8d00-4706-953f-60f38368f89a' User entered 'None (1)'	System	02 Oct 2020 01:19:37
	System	02 Oct 2020 01:19:37

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:32', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7621ffc3-8d00-4706-953f-60f38368f89a' User entered '01 Oct 2020 21:19'	System	02 Oct 2020 01:19:37
	System	02 Oct 2020 01:19:37

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 5'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '18ab7fe9-80f9-4623-bb35-3f43e07980bf'	System	03 Oct 2020 00:20:08
User entered 'None (1)'	System	03 Oct 2020 00:20:08

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '18ab7fe9-80f9-4623-bb35-3f43e07980bf' User entered 'No (N)'	System	03 Oct 2020 00:20:08
	System	03 Oct 2020 00:20:08

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:19:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '18ab7fe9-80f9-4623-bb35-3f43e07980bf' User entered 'No (N)'	System	03 Oct 2020 00:20:08
	System	03 Oct 2020 00:20:08

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '18ab7fe9-80f9-4623-bb35-3f43e07980bf'	System	03 Oct 2020 00:20:08
User entered 'None (1)'	System	03 Oct 2020 00:20:08

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:05', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '18ab7fe9-80f9-4623-bb35-3f43e07980bf' User entered '02 Oct 2020 20:20'	System	03 Oct 2020 00:20:08
	System	03 Oct 2020 00:20:08

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 6'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd8d73f0a-6ed3-43bc-a539-8f062e3ee57e'	System	04 Oct 2020 00:50:00
User entered 'None (1)'	System	04 Oct 2020 00:50:00

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:51', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd8d73f0a-6ed3-43bc-a539-8f062e3ee57e' User entered 'No (N)'	System	04 Oct 2020 00:50:00
	System	04 Oct 2020 00:50:00

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:53', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd8d73f0a-6ed3-43bc-a539-8f062e3ee57e' User entered 'No (N)'	System	04 Oct 2020 00:50:00
	System	04 Oct 2020 00:50:00

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd8d73f0a-6ed3-43bc-a539-8f062e3ee57e'	System	04 Oct 2020 00:50:00
User entered 'None (1)'	System	04 Oct 2020 00:50:00

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:49:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd8d73f0a-6ed3-43bc-a539-8f062e3ee57e' User entered '03 Oct 2020 20:49'	System	04 Oct 2020 00:50:00
	System	04 Oct 2020 00:50:00

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 7'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:18', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'bada488d-b339-4a3a-9ecc-55b5d1ce62d9'	System	05 Oct 2020 00:26:33
User entered 'None (1)'	System	05 Oct 2020 00:26:33

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:22', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'bada488d-b339-4a3a-9ecc-55b5d1ce62d9'	System	05 Oct 2020 00:26:33
User entered 'No (N)'	System	05 Oct 2020 00:26:33

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:25', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'bada488d-b339-4a3a-9ecc-55b5d1ce62d9' User entered 'No (N)'	System	05 Oct 2020 00:26:33
	System	05 Oct 2020 00:26:33

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:27', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'bada488d-b339-4a3a-9ecc-55b5d1ce62d9' User entered 'None (1)'	System	05 Oct 2020 00:26:33
	System	05 Oct 2020 00:26:33

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:31', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'bada488d-b339-4a3a-9ecc-55b5d1ce62d9' User entered '04 Oct 2020 20:26'	System	05 Oct 2020 00:26:33
	System	05 Oct 2020 00:26:33

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 11:50'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:42', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'None (0)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:53', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered 'No (N)'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-28T18:12:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '64f46778-39b1-4058-a97c-e7d4786396f3' User entered '28 Sep 2020 18:12'	System	28 Sep 2020 22:13:00
	System	28 Sep 2020 22:13:00

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 2'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:41', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:43', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:47', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:51', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:53', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:51:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'None (0)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:52:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered 'No (N)'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-29T19:52:03', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd195d8d5-e9f4-4230-80de-4e840d6c4e0a' User entered '29 Sep 2020 19:52'	System	29 Sep 2020 23:52:06
	System	29 Sep 2020 23:52:06

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 3'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:18', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:22', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:27', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:33', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'None (0)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered 'No (N)'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-09-30T21:27:48', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25bcfd06-ac41-47e1-84cc-7eb5fac07ca6' User entered '30 Sep 2020 21:27'	System	01 Oct 2020 01:27:50
	System	01 Oct 2020 01:27:50

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 4'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:39', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:41', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:47', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fdcaa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:54', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'None (0)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:19:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fd faa194920b' User entered 'No (N)'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-01T21:20:02', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'd58f2514-62e0-483d-9def-fdcaa194920b' User entered '01 Oct 2020 21:20'	System	02 Oct 2020 01:20:07
	System	02 Oct 2020 01:20:07

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 5'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:09', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:21', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'None (0)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:27', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered 'No (N)'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-02T20:20:30', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '649fb992-08fc-4da2-b2a5-b2473f795525' User entered '02 Oct 2020 20:20'	System	03 Oct 2020 00:20:35
	System	03 Oct 2020 00:20:35

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 6'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:02', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:07', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:09', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered 'None (0)'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:20', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658'	System	04 Oct 2020 00:50:26
User entered 'No (N)'	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-03T20:50:23', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'f79da96d-6aaf-4f1e-8c5e-686531bfa658' User entered '03 Oct 2020 20:50'	System	04 Oct 2020 00:50:26
	System	04 Oct 2020 00:50:26

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	28 Sep 2020 15:33:59
User entered 'Day 7'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:41', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:47', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:52', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'None (0)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered 'No (N)'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-10-04T20:26:59', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '81ae16a7-0dd7-4de9-a565-2d2dd0888b1f' User entered '04 Oct 2020 20:26'	System	05 Oct 2020 00:27:01
	System	05 Oct 2020 00:27:01

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:33:59

US3622116

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:10:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:33:59

US3622116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:56:56
User entered 'Yes (Y)'	Junlin Long	08 Oct 2020 17:22:08

US3622116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:56:56
User entered '5 Oct 2020'	Junlin Long	08 Oct 2020 17:22:08

US3622116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:56:56
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	08 Oct 2020 17:22:08

US3622116

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:56:56
User entered empty.	Junlin Long (b) (4)	08 Oct 2020 17:22:08

US3622116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:56:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Oct 2020 17:22:40

US3622116

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	08 Oct 2020 17:22:40

US3622116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Yes (Y)'	Junlin Long	13 Oct 2020 17:37:32

US3622116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '13 Oct 2020'	Junlin Long (b) (4)	13 Oct 2020 17:37:32

US3622116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	13 Oct 2020 17:37:32

US3622116

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long (b) (4)	13 Oct 2020 17:37:32

US3622116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Yes (Y)'	Junlin Long	13 Oct 2020 17:37:38

US3622116

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	13 Oct 2020 17:37:38

US3622116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:50:05
User entered 'Yes (Y)'	Junlin Long	20 Oct 2020 14:42:36

US3622116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:50:05
User entered '19 Oct 2020'	Junlin Long	20 Oct 2020 14:42:36

US3622116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:50:05
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	20 Oct 2020 14:42:36

US3622116

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:50:05
User entered empty.	Junlin Long (b) (4)	20 Oct 2020 14:42:36

US3622116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:50:05
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 14:42:40

US3622116

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:41
User entered 'I'	System	20 Oct 2020 14:42:40

US3622116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 14:16:42

US3622116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '26 Oct 2020'	Junlin Long	26 Oct 2020 14:16:42

US3622116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	26 Oct 2020 14:16:42

US3622116

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'VISIT3'	System	26 Oct 2020 14:16:42

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '26 Oct 2020'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '09:46'	Junlin Long	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '26 Oct 2020 09:46'	System	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '98.4' F	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Oral (Oral)'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '82'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'bpm'	System	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '20'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'breaths/min'	System	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '122'	Junlin Long (b) (4)	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '81'	Junlin Long	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'mmHg'	System	26 Oct 2020 14:17:08

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55

US3622116

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55

US3622116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'No (N)'	Junlin Long	26 Oct 2020 14:17:12

US3622116

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	Junlin Long	26 Oct 2020 14:17:12

US3622116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 14:17:24

US3622116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '26 Oct 2020'	Junlin Long (b) (4)	26 Oct 2020 14:17:24

US3622116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '09:50'	Junlin Long	26 Oct 2020 14:17:24

US3622116

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered '26 Oct 2020 09:50'	System	26 Oct 2020 14:17:24

US3622116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Yes (Y)'	Junlin Long	26 Oct 2020 14:17:27

US3622116

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'I'	System	26 Oct 2020 14:17:27

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 64'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-03T05:47:38', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6614c857-0d52-403e-b503-72be4c77d46f' User entered 'No (N)'	System	03 Nov 2020 10:47:54
	System	03 Nov 2020 10:47:54

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-03T05:47:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6614c857-0d52-403e-b503-72be4c77d46f' User entered 'No (N)'	System	03 Nov 2020 10:47:54
	System	03 Nov 2020 10:47:54

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-03T05:47:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6614c857-0d52-403e-b503-72be4c77d46f' User entered '03 Nov 2020 05:47:49'	System	03 Nov 2020 10:47:54
	System	03 Nov 2020 10:47:54

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 71'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-10T06:46:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '09c32e66-a817-48e3-870c-ff2dea1e733d' User entered 'No (N)'	System	10 Nov 2020 11:47:02
	System	10 Nov 2020 11:47:02

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-10T06:46:55', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '09c32e66-a817-48e3-870c-ff2dea1e733d' User entered 'No (N)'	System	10 Nov 2020 11:47:02
	System	10 Nov 2020 11:47:02

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-10T06:46:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '09c32e66-a817-48e3-870c-ff2dea1e733d' User entered '10 Nov 2020 06:46:58'	System	10 Nov 2020 11:47:02
	System	10 Nov 2020 11:47:02

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered 'Day 78'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-16T19:41:24', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c628974-3f11-4ed8-b24a-39d1c051b650'	System	17 Nov 2020 00:41:42
User entered 'No (N)'	System	17 Nov 2020 00:41:42

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-16T19:41:28', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c628974-3f11-4ed8-b24a-39d1c051b650'	System	17 Nov 2020 00:41:42
User entered 'No (N)'	System	17 Nov 2020 00:41:42

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-16T19:41:38', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '6c628974-3f11-4ed8-b24a-39d1c051b650' User entered '16 Nov 2020 19:41:38'	System	17 Nov 2020 00:41:42
	System	17 Nov 2020 00:41:42

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:19:08

US3622116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:00:38
Data entry locked.	System	31 Aug 2020 15:19:08
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:19:08

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-25T06:52:03', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7c60de7a-ebd7-4d87-990b-689fee8dcdfb' User entered 'No (N)'	System	25 Nov 2020 11:52:39

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-25T06:52:31', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7c60de7a-ebd7-4d87-990b-689fee8dcdfb'	System	25 Nov 2020 11:52:39
User entered 'No (N)'	System	25 Nov 2020 11:52:39

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-11-25T06:52:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7c60de7a-ebd7-4d87-990b-689fee8dcdfb' User entered '25 Nov 2020 06:52:34'	System	25 Nov 2020 11:52:39
	System	25 Nov 2020 11:52:39

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-02T00:06:05', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9c0854b2-d977-4a53-b0e6-9b1be63eb09c' User entered 'No (N)'	System	02 Dec 2020 05:06:16
	System	02 Dec 2020 05:06:16

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-02T00:06:10', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9c0854b2-d977-4a53-b0e6-9b1be63eb09c'	System	02 Dec 2020 05:06:16
User entered 'No (N)'	System	02 Dec 2020 05:06:16

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-02T00:06:14', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '9c0854b2-d977-4a53-b0e6-9b1be63eb09c' User entered '02 Dec 2020 00:06:14'	System	02 Dec 2020 05:06:16
	System	02 Dec 2020 05:06:16

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-09T19:25:26', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '30de852e-4121-44e7-b9aa-b22c860bd78f' User entered 'No (N)'	System	10 Dec 2020 00:25:38
	System	10 Dec 2020 00:25:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-09T19:25:31', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '30de852e-4121-44e7-b9aa-b22c860bd78f' User entered 'No (N)'	System	10 Dec 2020 00:25:38
	System	10 Dec 2020 00:25:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-09T19:25:35', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '30de852e-4121-44e7-b9aa-b22c860bd78f' User entered '09 Dec 2020 19:25:35'	System	10 Dec 2020 00:25:38
	System	10 Dec 2020 00:25:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-16T18:49:07', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '57d9a926-7580-4b29-8a8b-f04598d935db'	System	16 Dec 2020 23:49:19
User entered 'No (N)'	System	16 Dec 2020 23:49:19

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-16T18:49:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '57d9a926-7580-4b29-8a8b-f04598d935db'	System	16 Dec 2020 23:49:19
User entered 'No (N)'	System	16 Dec 2020 23:49:19

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-16T18:49:15', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '57d9a926-7580-4b29-8a8b-f04598d935db' User entered '16 Dec 2020 18:49:15'	System	16 Dec 2020 23:49:19
	System	16 Dec 2020 23:49:19

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-23T08:13:36', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'dc0c58e8-8057-43aa-a7ea-96d1b074caac'	System	23 Dec 2020 13:13:57
User entered 'No (N)'	System	23 Dec 2020 13:13:57

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-23T08:13:45', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'dc0c58e8-8057-43aa-a7ea-96d1b074caac'	System	23 Dec 2020 13:13:57
User entered 'No (N)'	System	23 Dec 2020 13:13:57

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-23T08:13:51', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'dc0c58e8-8057-43aa-a7ea-96d1b074caac' User entered '23 Dec 2020 08:13:51'	System	23 Dec 2020 13:13:57
	System	23 Dec 2020 13:13:57

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-30T12:27:50', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '4f922f7e-cf31-4664-afff-a3f14ce9de1c' User entered 'No (N)'	System	30 Dec 2020 17:28:10
	System	30 Dec 2020 17:28:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-30T12:28:01', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '4f922f7e-cf31-4664-afff-a3f14ce9de1c' User entered 'No (N)'	System	30 Dec 2020 17:28:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2020-12-30T12:28:04', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '4f922f7e-cf31-4664-afff-a3f14ce9de1c' User entered '30 Dec 2020 12:28:04'	System	30 Dec 2020 17:28:10
	System	30 Dec 2020 17:28:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-06T07:07:05', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7527ab49-1916-4feb-89cb-5085fcdaba9f' User entered 'No (N)'	System	06 Jan 2021 12:07:15
	System	06 Jan 2021 12:07:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-06T07:07:08', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7527ab49-1916-4feb-89cb-5085fcdaba9f'	System	06 Jan 2021 12:07:15
User entered 'No (N)'	System	06 Jan 2021 12:07:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-06T07:07:11', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '7527ab49-1916-4feb-89cb-5085fcdaba9f' User entered '06 Jan 2021 07:07:11'	System	06 Jan 2021 12:07:15
	System	06 Jan 2021 12:07:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-13T06:29:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2af51fd5-7d42-449f-9c0c-a6bce8e14842'	System	13 Jan 2021 11:29:23
User entered 'No (N)'	System	13 Jan 2021 11:29:23

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-13T06:29:16', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2af51fd5-7d42-449f-9c0c-a6bce8e14842'	System	13 Jan 2021 11:29:23
User entered 'No (N)'	System	13 Jan 2021 11:29:23

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-13T06:29:19', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2af51fd5-7d42-449f-9c0c-a6bce8e14842'	System	13 Jan 2021 11:29:23
User entered '13 Jan 2021 06:29:19'	System	13 Jan 2021 11:29:23

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-22T20:20:34', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2248913d-f642-45d2-b667-be66283cb451' User entered 'No (N)'	System	23 Jan 2021 01:20:43

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-22T20:20:37', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2248913d-f642-45d2-b667-be66283cb451'	System	23 Jan 2021 01:20:43
User entered 'No (N)'	System	23 Jan 2021 01:20:43

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-22T20:20:40', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '2248913d-f642-45d2-b667-be66283cb451' User entered '22 Jan 2021 20:20:40'	System	23 Jan 2021 01:20:43

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-28T17:08:44', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25174be2-e696-4852-a77c-19b014155a16'	System	28 Jan 2021 22:08:51
User entered 'No (N)'	System	28 Jan 2021 22:08:51

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-28T17:08:46', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25174be2-e696-4852-a77c-19b014155a16'	System	28 Jan 2021 22:08:51
User entered 'No (N)'	System	28 Jan 2021 22:08:51

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-01-28T17:08:49', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '25174be2-e696-4852-a77c-19b014155a16'	System	28 Jan 2021 22:08:51
User entered '28 Jan 2021 17:08:49'	System	28 Jan 2021 22:08:51

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-03T06:41:58', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5cbc5b33-34a0-4598-a119-11b9e3b6f68a' User entered 'No (N)'	System	03 Feb 2021 11:42:05
	System	03 Feb 2021 11:42:05

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-03T06:42:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5cbc5b33-34a0-4598-a119-11b9e3b6f68a' User entered 'No (N)'	System	03 Feb 2021 11:42:05
	System	03 Feb 2021 11:42:05

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-03T06:42:03', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '5cbc5b33-34a0-4598-a119-11b9e3b6f68a' User entered '03 Feb 2021 06:42:03'	System	03 Feb 2021 11:42:05
	System	03 Feb 2021 11:42:05

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-10T19:58:54', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '1d92b019-7866-4b4f-8950-ed0984416018' User entered 'No (N)'	System	11 Feb 2021 00:59:01
	System	11 Feb 2021 00:59:01

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-10T19:58:56', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '1d92b019-7866-4b4f-8950-ed0984416018' User entered 'No (N)'	System	11 Feb 2021 00:59:01

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-10T19:58:59', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '1d92b019-7866-4b4f-8950-ed0984416018'	System	11 Feb 2021 00:59:01
User entered '10 Feb 2021 19:58:59'	System	11 Feb 2021 00:59:01

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-17T06:56:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '87e19219-560e-4961-ba30-f13b61c323e6' User entered 'No (N)'	System	17 Feb 2021 11:56:15
	System	17 Feb 2021 11:56:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-17T06:56:07', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '87e19219-560e-4961-ba30-f13b61c323e6' User entered 'No (N)'	System	17 Feb 2021 11:56:15
	System	17 Feb 2021 11:56:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-17T06:56:12', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '87e19219-560e-4961-ba30-f13b61c323e6' User entered '17 Feb 2021 06:56:12'	System	17 Feb 2021 11:56:15
	System	17 Feb 2021 11:56:15

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-25T06:56:56-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '3c61fcb9-4294-4e7b-949e-c369ce1c1e52'	System	25 Feb 2021 11:57:07
User entered 'No (N)'	System	25 Feb 2021 11:57:07

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-25T06:56:58-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '3c61fcb9-4294-4e7b-949e-c369ce1c1e52'	System	25 Feb 2021 11:57:07
User entered 'No (N)'	System	25 Feb 2021 11:57:07

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-25T06:57:03-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '3c61fcb9-4294-4e7b-949e-c369ce1c1e52' User entered '25 Feb 2021 11:57:03'	System	25 Feb 2021 11:57:07
	System	25 Feb 2021 11:57:07

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-05T15:56:06-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '113303a4-e3fd-4f32-bcee-da86d6e28fa2'	System	05 Mar 2021 22:15:06
User entered 'No (N)'	System	05 Mar 2021 22:15:06

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-05T15:56:09-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '113303a4-e3fd-4f32-bcee-da86d6e28fa2'	System	05 Mar 2021 22:15:06
User entered 'No (N)'	System	05 Mar 2021 22:15:06

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-05T15:56:13-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '113303a4-e3fd-4f32-bcee-da86d6e28fa2' User entered '05 Mar 2021 15:56:13'	System	05 Mar 2021 22:15:06
	System	05 Mar 2021 22:15:06

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-10T06:39:01-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a458e831-6b2b-4d85-8f2e-c1d93d3237d2'	System	10 Mar 2021 11:39:12
User entered 'No (N)'	System	10 Mar 2021 11:39:12

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-10T06:39:05-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a458e831-6b2b-4d85-8f2e-c1d93d3237d2'	System	10 Mar 2021 11:39:12
User entered 'No (N)'	System	10 Mar 2021 11:39:12

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-10T06:39:09-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a458e831-6b2b-4d85-8f2e-c1d93d3237d2' User entered '10 Mar 2021 06:39:09'	System	10 Mar 2021 11:39:12
	System	10 Mar 2021 11:39:12

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-18T06:12:50-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '79bfc79f-3664-4512-8cf1-bbd919d7d549'	System	18 Mar 2021 10:13:10
User entered 'No (N)'	System	18 Mar 2021 10:13:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-18T06:12:54-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '79bfc79f-3664-4512-8cf1-bbd919d7d549'	System	18 Mar 2021 10:13:10
User entered 'No (N)'	System	18 Mar 2021 10:13:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-03-18T06:12:57-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '79bfc79f-3664-4512-8cf1-bbd919d7d549' User entered '18 Mar 2021 06:12:57'	System	18 Mar 2021 10:13:10
	System	18 Mar 2021 10:13:10

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-01T06:57:27-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '575d81d4-242c-47a2-b4e2-ff711b10fbb0' User entered 'No (N)'	System	01 Apr 2021 10:57:38
	System	01 Apr 2021 10:57:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-01T06:57:31-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '575d81d4-242c-47a2-b4e2-ff711b10fbb0' User entered 'No (N)'	System	01 Apr 2021 10:57:38
	System	01 Apr 2021 10:57:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-01T06:57:34-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '575d81d4-242c-47a2-b4e2-ff711b10fbb0' User entered '01 Apr 2021 06:57:34'	System	01 Apr 2021 10:57:38
	System	01 Apr 2021 10:57:38

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-09T20:50:47-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '37ef20d1-bb95-4a93-835e-a2429d7bc9a3'	System	10 Apr 2021 00:51:00
User entered 'No (N)'	System	10 Apr 2021 00:51:00

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-09T20:50:52-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '37ef20d1-bb95-4a93-835e-a2429d7bc9a3'	System	10 Apr 2021 00:51:00
User entered 'No (N)'	System	10 Apr 2021 00:51:00

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-09T20:50:55-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '37ef20d1-bb95-4a93-835e-a2429d7bc9a3'	System	10 Apr 2021 00:51:00
User entered '09 Apr 2021 20:50:55'	System	10 Apr 2021 00:51:00

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-14T18:40:31-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '184d40eb-a56e-4f91-a054-621dbc287cf5'	System	14 Apr 2021 22:40:40
User entered 'No (N)'	System	14 Apr 2021 22:40:40

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-14T18:40:34-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '184d40eb-a56e-4f91-a054-621dbc287cf5'	System	14 Apr 2021 22:40:40
User entered 'No (N)'	System	14 Apr 2021 22:40:40

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-14T18:40:37-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '184d40eb-a56e-4f91-a054-621dbc287cf5'	System	14 Apr 2021 22:40:40
User entered '14 Apr 2021 18:40:37'	System	14 Apr 2021 22:40:40

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-21T07:55:42-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '29ff5ebd-9bbe-40b9-a3f0-d8b3559e93f4'	System	21 Apr 2021 11:55:55
User entered 'No (N)'	System	21 Apr 2021 11:55:55

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-21T07:55:25-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '29ff5ebd-9bbe-40b9-a3f0-d8b3559e93f4'	System	21 Apr 2021 11:55:55
User entered 'No (N)'	System	21 Apr 2021 11:55:55

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-21T07:55:51-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '29ff5ebd-9bbe-40b9-a3f0-d8b3559e93f4'	System	21 Apr 2021 11:55:55
User entered '21 Apr 2021 07:55:51'	System	21 Apr 2021 11:55:55

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-29T06:39:49-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a42afd10-b28d-4803-b481-964b610b14b4'	System	29 Apr 2021 10:39:58
User entered 'No (N)'	System	29 Apr 2021 10:39:58

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-29T06:39:52-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a42afd10-b28d-4803-b481-964b610b14b4'	System	29 Apr 2021 10:39:58
User entered 'No (N)'	System	29 Apr 2021 10:39:58

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-04-29T06:39:55-04:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: 'a42afd10-b28d-4803-b481-964b610b14b4'	System	29 Apr 2021 10:39:58
User entered '29 Apr 2021 06:39:55'	System	29 Apr 2021 10:39:58

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:50:22

US3622116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:10:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:50:22
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:50:22

US3622116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:10:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:24:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-28T17:28:29-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '19817947-2c68-4278-b3e7-26d962587b07'	System	28 Feb 2021 22:28:37
User entered 'No (N)'	System	28 Feb 2021 22:28:37

US3622116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:10:42

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:24:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (987BF796-15A1-40B1-BDB0-9A4DCC80D69A)', Time: '2021-02-28T17:28:35-05:00', User OID: 'PatientReportedOutcome (US3622116)', ODM File OID: '19817947-2c68-4278-b3e7-26d962587b07'	System	28 Feb 2021 22:28:37
User entered '28 Feb 2021 17:28:35'	System	28 Feb 2021 22:28:37

US3622116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Yes (Y)'	Junlin Long	24 Nov 2020 19:20:55

US3622116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered '24 Nov 2020'	Junlin Long (b) (4)	24 Nov 2020 19:20:55

US3622116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	24 Nov 2020 19:20:55

US3622116

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	24 Nov 2020 19:20:55

US3622116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Yes (Y)'	Junlin Long (b) (4)	24 Nov 2020 19:20:58

US3622116

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:33:55
User entered 'I'	System	24 Nov 2020 19:20:58

US3622116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Yes (Y)'	Junlin Long	28 Dec 2020 19:50:46

US3622116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered '28 Dec 2020'	Junlin Long (b) (4)	28 Dec 2020 19:50:46

US3622116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	28 Dec 2020 19:50:46

US3622116

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered empty.	Junlin Long (b) (4)	28 Dec 2020 19:50:46

US3622116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Dec 2020 19:50:51

US3622116

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'I'	System	28 Dec 2020 19:50:51

US3622116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 19:48:25

US3622116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '26 Jan 2021'	Junlin Long	26 Jan 2021 19:48:25

US3622116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	26 Jan 2021 19:48:25

US3622116

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 19:48:25

US3622116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 19:48:28

US3622116

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'I'	System	26 Jan 2021 19:48:28

US3622116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Yes (Y)'	Junlin Long	24 Feb 2021 18:24:55

US3622116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered '24 Feb 2021'	Junlin Long (b) (4)	24 Feb 2021 18:24:55

US3622116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	24 Feb 2021 18:24:55

US3622116

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered empty.	Junlin Long (b) (4)	24 Feb 2021 18:24:55

US3622116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Yes (Y)'	Junlin Long (b) (4)	24 Feb 2021 18:24:58

US3622116

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'I'	System	24 Feb 2021 18:24:58

US3622116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Yes (Y)'	Junlin Long	30 Mar 2021 16:06:30

US3622116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '30 Mar 2021'	Junlin Long	30 Mar 2021 16:06:30

US3622116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Clinic (Clinic)'	Junlin Long	30 Mar 2021 16:06:30

US3622116

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'VISIT4'	System	30 Mar 2021 16:06:30

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Yes (Y)'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '30 Mar 2021'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '11:16'	Junlin Long (b) (4)	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered '30 Mar 2021 11:16'	System	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '98.9' F	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Oral (Oral)'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered empty.	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '101'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'bpm'	System	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '18'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'breaths/min'	System	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '118'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'mmHg'	System	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '92'	Junlin Long	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'mmHg'	System	30 Mar 2021 16:06:54

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29

US3622116

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29

US3622116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'No (N)'	Junlin Long	30 Mar 2021 16:07:00

US3622116

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered empty.	Junlin Long	30 Mar 2021 16:07:00

US3622116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Yes (Y)'	Junlin Long	30 Mar 2021 16:07:10

US3622116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '30 Mar 2021'	Junlin Long	30 Mar 2021 16:07:10

US3622116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered '11:35'	Junlin Long	30 Mar 2021 16:07:10

US3622116

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered '30 Mar 2021 11:35'	System	30 Mar 2021 16:07:10

US3622116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User entered 'Yes (Y)'	Junlin Long	30 Mar 2021 16:07:13

US3622116

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:45:29
User entered 'I'	System	30 Mar 2021 16:07:13

US3622116

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	19 Jan 2021 18:56:44

US3622116

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long	19 Jan 2021 18:56:44

US3622116

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	19 Jan 2021 18:56:44

US3622116

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

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:56:44

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:10:55
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:02:35

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:10:55
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:02:35

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:27:13
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	19 Jan 2021 18:56:55
	(b) (4)	

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:27:13
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	19 Jan 2021 18:56:55
	(b) (4)	

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '1'	System	19 Jan 2021 18:56:55

US3622116

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

Form: Unblinding

Generated On: 10 Jun 2021 09:10:42

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'I'	System	19 Jan 2021 18:56:55

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '65' in	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '167' lb	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '27.84836'	System	19 Jan 2021 19:40:10
DataPoint set to visible.	System	19 Jan 2021 18:56:55

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '65' in	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '167' lb	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '27.84836'	System	19 Jan 2021 19:40:10
DataPoint set to visible.	System	19 Jan 2021 18:56:55

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	19 Jan 2021 19:40:10
	(b) (4)	

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '12:48'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '19 Jan 2021 12:48'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '98.2' F	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Oral (Oral)'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '96'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'bpm'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '20'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'breaths/min'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '127'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '97'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '65' in	Junlin Long	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '167' lb	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:10:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '27.84836'	System	19 Jan 2021 19:40:10
DataPoint set to visible.	System	19 Jan 2021 18:56:55

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '14:09'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '19 Jan 2021 14:09'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '97.5' F	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Oral (Oral)'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '89'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'bpm'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '16'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'breaths/min'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '109'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '83'	Junlin Long (b) (4)	19 Jan 2021 19:40:10

US3622116

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	19 Jan 2021 19:40:10

US3622116

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'No (N)'	Junlin Long	19 Jan 2021 19:40:15

US3622116

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long	19 Jan 2021 19:40:15

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mRNA-1273'	System	19 Jan 2021 18:57:07
DataPoint set to visible.	System	19 Jan 2021 18:56:55

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '13:36'	Junlin Long	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '19 Jan 2021 13:36'	System	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'ONCE'	System	19 Jan 2021 18:57:07

US3622116

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

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 18:57:07

US3622116

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 19:40:26

US3622116

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 19:40:26

US3622116

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '13:05'	Junlin Long	19 Jan 2021 19:40:26

US3622116

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '19 Jan 2021 13:05'	System	19 Jan 2021 19:40:26

US3622116

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 19:40:33

US3622116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 19:40:33

US3622116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '13:10'	Junlin Long (b) (4)	19 Jan 2021 19:40:33

US3622116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:10:42

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '19 Jan 2021 13:10'	System	19 Jan 2021 19:40:33

US3622116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Jan 2021 19:40:39

US3622116

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '1'	System	19 Jan 2021 19:40:39

US3622116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 19:48:37

US3622116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '26 Jan 2021'	Junlin Long	26 Jan 2021 19:48:37

US3622116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	26 Jan 2021 19:48:37

US3622116

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered empty.	Junlin Long	26 Jan 2021 19:48:37

US3622116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered 'Yes (Y)'	Junlin Long	26 Jan 2021 19:48:39

US3622116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User entered 'I'	System	26 Jan 2021 19:48:39

US3622116

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:42
User entered '1'	System	26 Jan 2021 19:48:39
DataPoint set to visible.	System	26 Jan 2021 19:48:39

US3622116

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Yes (Y)'	Junlin Long	16 Feb 2021 16:19:07

US3622116

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '16 Feb 2021'	Junlin Long (b) (4)	16 Feb 2021 16:19:07

US3622116

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	16 Feb 2021 16:19:07

US3622116

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'OLD29'	System	16 Feb 2021 16:19:07

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Feb 2021 16:48:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 16:48:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 16:48:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 16:48:35
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '10:34'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '16 Feb 2021 10:34'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '99'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'bpm'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'breaths/min'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '135'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '96'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '11:28'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '16 Feb 2021 11:28'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '95'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'bpm'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'breaths/min'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '124'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '103'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mmHg'	System	16 Feb 2021 16:48:35

US3622116

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:53

US3622116

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:48:53

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Yes (Y)'	Junlin Long	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered empty.	Junlin Long	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered empty.	Junlin Long (b) (4)	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'mRNA-1273'	System	16 Feb 2021 16:19:21
DataPoint set to visible.	System	26 Jan 2021 19:48:39

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '16 Feb 2021'	Junlin Long	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered '10:56'	Junlin Long	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered '16 Feb 2021 10:56'	System	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Left Arm (LEFT ARM)'	Junlin Long	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'ONCE'	System	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:10:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:19:21

US3622116

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:49:03

US3622116

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:54:19
User entered 'I'	System	16 Feb 2021 16:49:03

US3622116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Yes (Y)'	Junlin Long (b) (4)	23 Feb 2021 14:00:10

US3622116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered '23 Feb 2021'	Junlin Long	23 Feb 2021 14:00:10

US3622116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	23 Feb 2021 14:00:10

US3622116

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:10:42

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered empty.	Junlin Long (b) (4)	23 Feb 2021 14:00:10

US3622116

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Yes (Y)'	Junlin Long	23 Feb 2021 14:00:16

US3622116

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:10:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:44:44
User entered 'I'	System	23 Feb 2021 14:00:16

US3622116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:24

US3622116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:24

US3622116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:01:24

US3622116

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:10:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered 'OLD57'	System	23 Mar 2021 19:01:24

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '11:47'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered '23 Mar 2021 11:47'	System	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '98'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered 'bpm'	System	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '20'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered 'breaths/min'	System	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '138'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered 'mmHg'	System	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered 'mmHg'	System	23 Mar 2021 19:02:09

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59

US3622116

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:10:42

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59

US3622116

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:17

US3622116

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:10:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:17

US3622116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:33

US3622116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:33

US3622116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
User entered '12:00'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:02:33

US3622116

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:10:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:59
User entered '23 Mar 2021 12:00'	System	23 Mar 2021 19:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:10:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long (b) (4)	30 Sep 2020 16:38:40

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:24:29
User closed query 'Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:24:19
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'Unknown' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:55:05
Query 'Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you ' answered with 'according to lab results of visit 2 and 3 that happened during this time frame, participant was covid-19 negative.' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Apr 2021 12:00:13
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:55:19
User opened query 'Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:41:14
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:41:14

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'according to lab results of visits that happened during this time frame, participant was covid-19 negative.' (Site from DM).	Junlin Long (b) (4) (b) (4)	30 Mar 2021 14:16:40
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4), (b) (6) (b) (4)	30 Mar 2021 07:21:02
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 12:06:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Tiredness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:06:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 01:06:21
Data point term sent to Coder	System	30 Sep 2020 16:40:05
User entered 'tired feeling'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '18 Sep 2020'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	30 Sep 2020 16:39:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
User entered empty.	System	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
Signature has been broken.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:36:24
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Dec 2020 16:11:12
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 00:38:14
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:20:52
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:20:52
User entered '24 Nov 2020' reason for change: New Information	(b) (4)	04 Mar 2021 18:20:52
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	30 Sep 2020 16:39:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	30 Sep 2020 16:39:30
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
User entered empty.	System	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	30 Sep 2020 16:39:30
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

US3622116

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'None (NONE)'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
Signature has been broken.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:20:52
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	30 Sep 2020 16:39:30
	(b) (4)	

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long (b) (4)	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
User entered '0'	System	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35
User entered '0'	System	30 Sep 2020 16:39:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
User closed query ' Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 05:36:06
Query ' Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you' answered with 'according to lab results of visit 2 and 3 that happened during this time frame, participant was covid-19 negative.' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Apr 2021 12:01:37
User opened query ' Per CDM: Per response "according ...negative" However, the corresponding Covid-19 Assessment is not yet recorded. Please confirm and update or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:42:05
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:42:05
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'according to lab results of visits that happened during this time frame, participant was covid-19 negative.' (Site from DM).	Junlin Long (b) (4) (b) (4)	30 Mar 2021 14:17:11
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:21:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 19:55:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia upper extremities - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:52:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:52:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	13 Oct 2020 17:40:14
User entered 'bilateral upper extremity muscle aches'	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '30 Sep 2020'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
User entered empty.	System	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:21:12
Signature has been broken.	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:21:12
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	04 Mar 2021 18:21:12
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:36:34
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'still ongoing' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Dec 2020 16:11:24
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 00:38:22
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:21:12
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:21:12
User entered '28 Dec 2020' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
User entered empty.	System	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'None (NONE)'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:21:12
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:21:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:21:12
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:03
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long (b) (4)	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
User entered '0'	System	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38
User entered '0'	System	13 Oct 2020 17:40:03

US3622116

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:38

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 17:42:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:42:21
Data point term sent to Coder	System	13 Oct 2020 17:41:15
User entered 'insomnia'	Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '24 Sep 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Yes (Y)'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'None (NONE)'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'I'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered '0'	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:55:18
User entered empty.	Junlin Long	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 17:40:47

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:06:31
User entered 'USA-US085-2020-mRNA-1273-P301000003'	System	03 Dec 2020 15:06:24
User entered 'New'	(b) (4), (b) (6)	03 Dec 2020 15:06:24

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:48:23
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'this subject was not assessed for potential COVID-19 infection.' (Site from DM).	Junlin Long (b) (4) (b) (4)	15 Feb 2021 17:35:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:09:40
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:10:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:10:45
Data point term sent to Coder	System	02 Dec 2020 19:09:49
User entered 'vomiting'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 15:59:49
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '3 Dec 2020' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 15:59:49
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
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).		02 Dec 2020 19:28:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		02 Dec 2020 19:28:14
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Dec 2020 19:09:00
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '2 Dec 2020' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:28:14
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	02 Dec 2020 19:29:59
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		02 Dec 2020 19:29:59
User entered 'No (N)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:29:59
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	02 Dec 2020 19:09:00
User entered 'Unknown (UNK)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:30:47
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'conmed updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:27:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:17:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:46:02
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4)	23 Feb 2021 20:08:35
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:33:51
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 15:59:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:16:23
Query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' answered with 'participant signed ama, so etiology cannot be obtained.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:52:49
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:47:15
User entered 'PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:47:15

update: Patient presented to the ER on 12/01/2020 with right lower quadrant abdominal pain that was present x 2 days. In addition, he reported several episodes of vomiting, and loss of consciousness. He underwent a CT scan of the abdomen and pelvis W/WO contrast which revealed multiple areas of attenuation consistent with liver cysts. Chest X-ray which was normal and an US of the liver which revealed multiple cysts with the largest measuring 1.8cm. Labs revealed total bilirubin was above normal limits at 1.40 mg/dl. He was admitted for further evaluation. The patient left the hospital AMA on 12/02/2020.' reason for change: New Information

User opened query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:46:27
User closed query 'PV Query: The subject was discharged from hospital on 02 Dec 2020. The events, vomiting and nausea, was reported as resolved on 03 Dec 2020. Please confirm the end date of events vomiting and nausea since patient was discharged on 02 Dec 2020. ' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 18:49:31

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
Query 'PV Query: The subject was discharged from hospital on 02 Dec 2020. The events, vomiting and nausea, was reported as resolved on 03 Dec 2020. Please confirm the end date of events vomiting and nausea since patient was discharged on 02 Dec 2020. ' answered with 'participant was discharged from hospital on December 2nd, 2020. symptoms fully stopped on December 3rd, 2020.' (Site from Safety). User opened query 'PV Query: The subject was discharged from hospital on 02 Dec 2020. The events, vomiting and nausea, was reported as resolved on 03 Dec 2020. Please confirm the end date of events vomiting and nausea since patient was discharged on 02 Dec 2020. ' (Site from Safety). User entered 'PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29th TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.' reason for change: Data Entry Error User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). User entered 'participant called today to report that he had been hospitalized from November 29t to December 2nd, 2020, due to 6 episodes of vomiting and loss of consciousness.' reason for change: Data Entry Error User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). User entered empty.	Junlin Long (b) (4) (b) (4) (b) (4), (b) (6) (b) (4) (b) (4) System System Junlin Long (b) (4) (b) (4) System Junlin Long (b) (4) (b) (4)	14 Dec 2020 17:44:45 14 Dec 2020 16:32:30 02 Dec 2020 19:35:35 02 Dec 2020 19:28:14 02 Dec 2020 19:28:14 02 Dec 2020 19:28:14 02 Dec 2020 19:09:00 02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 19:09:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 19:09:00

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:06:51
User entered 'USA-US085-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	03 Dec 2020 15:06:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query: Please consider updating the event terms to the final diagnosis, when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:45:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
Query 'PV Query: Please consider updating the event terms to the final diagnosis, when available. ' answered with 'according to this participant's medical records, the final diagnosis was right lower quadrant abdominal pain (RLQ abd pain).' (Site from Safety).	Junlin Long (b) (4) (b) (4)	14 Dec 2020 17:49:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 17:48:40
Data point term sent to Coder	System	14 Dec 2020 17:48:05
Coding entries removed.	Junlin Long (b) (4) (b) (4)	14 Dec 2020 17:47:54
User entered 'RIGHT lower QUADRANT ABDOMINAL PAIN' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	14 Dec 2020 17:47:54
User opened query 'PV Query: Please consider updating the event terms to the final diagnosis, when available. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:13:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Right upper quadrant pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 09:33:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 09:33:55
Data point term sent to Coder	System	02 Dec 2020 19:35:25
User entered 'right upper quadrant abdominal pain'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Un-verified.	Junlin Long (b) (4)	26 Jan 2021 19:31:01
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	26 Jan 2021 19:31:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:35:23
Query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:20
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:01
User entered '16 Dec 2020' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:01
User opened query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:13:30
Query 'PV Query: Please provide the event (right upper quadrant abdominal pain) end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:13:26
User opened query 'PV Query: Please provide the event (right upper quadrant abdominal pain) end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:02:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event (right upper quadrant abdominal pain) end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:02:44
User opened query 'PV Query: Please provide the event (right upper quadrant abdominal pain) end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:14:17
User entered empty.	System	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '2 Dec 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 03:35:24
Query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' answered with 'conmed updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:32:08
User opened query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 16:48:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:46:34
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4)	23 Feb 2021 20:08:52
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:34:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:35:32
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'outcome provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:36
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:31:01
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:13:40
Query 'PV Query: Please provide the final event outcome for right upper quadrant abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:13:37
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User opened query 'PV Query: Please provide the final event outcome for right upper quadrant abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:13:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:17:05
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:16:48
Query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' answered with 'participant signed ama, so etiology cannot be obtained.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:53:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'medications and procedures have been updated.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:53:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:42:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'narrative updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:43:52
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:43:36

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS. update: Patient presented to the ER on 12/01/2020 with right lower quadrant abdominal pain that was present x 2 days. In addition, he reported several episodes of vomiting, and loss of consciousness. He underwent a CT scan of the abdomen and pelvis W/WO contrast which revealed multiple areas of attenuation consistent with liver cysts. Chest X-ray which was normal and an US of the liver which revealed multiple cysts with the largest measuring 1.8cm. Labs revealed total bilirubin was above normal limits at 1.40 mg/dl. He was admitted for further evaluation. The patient left the hospital AMA on 12/02/2020.' reason for change: New Information	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:43:36
User opened query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:45:32
Query 'PV Query: Please consider updating the event terms to the final diagnosis, when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:04:36
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User opened query 'PV Query: Please consider updating the event terms to the final diagnosis, when available. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:16:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:15:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 11:14:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'participant called today to report that he Junlin Long (b) (4) had been hospitalized from November 29th to December 2nd, 2020, due to 6 episodes of vomiting and loss of consciousness.'	(b) (4)	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 19:35:15

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:10
User entered 'USA-US085-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	03 Dec 2020 15:07:07

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Loss of consciousness, LLT: Loss of consciousness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:52
Data point term sent to Coder	System	02 Dec 2020 19:37:26
User entered 'loss of consciousness'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User entered empty.	System	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:04:00
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Please review the stop date recorded as it is not expected for this medical condition to have a duration of more than one day. Effects may last for days but not this condition itself. Review and record any effect of this as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:31:21
Query 'Per DM CLR: Please review the stop date recorded as it is not expected for this medical condition to have a duration of more than one day. Effects may last for days but not this condition itself. Review and record any effect of this as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:40:10
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:40:04
User entered '29 Nov 2020' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:40:04
User opened query 'Per DM CLR: Please review the stop date recorded as it is not expected for this medical condition to have a duration of more than one day. Effects may last for days but not this condition itself. Review and record any effect of this as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:17:29
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '30 Nov 2020' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:04:00
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User entered empty.	System	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Dec 2020 19:40:17
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Dec 2020 19:36:48
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Dec 2020 19:40:17
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).	System	02 Dec 2020 19:40:17
User entered '1' reason for change: Data Entry Error	Junlin Long (b) (4)	02 Dec 2020 19:40:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	02 Dec 2020 19:36:48
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '2 Dec 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

None

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Un-verified.	(b) (4) Junlin Long (b) (4)	26 Jan 2021 19:41:01
User entered '1' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	26 Jan 2021 19:41:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:31:31
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:41:05
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:41:01
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:41:01
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	14 Jan 2021 07:17:37
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '1'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:04:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:21:48
Query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' answered with 'participant signed ama, so etiology cannot be obtained.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:53:31
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:47:42
User entered 'PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:47:42
update: Patient presented to the ER on 12/01/2020 with right lower quadrant abdominal pain that was present x 2 days. In addition, he reported several episodes of vomiting, and loss of consciousness. He underwent a CT scan of the abdomen and pelvis W/WO contrast which revealed multiple areas of attenuation consistent with liver cysts. Chest X-ray which was normal and an US of the liver which revealed multiple cysts with the largest measuring 1.8cm. Labs revealed total bilirubin was above normal limits at 1.40 mg/dl. He was admitted for further evaluation. The patient left the hospital AMA on 12/02/2020.' reason for change: New Information		
User opened query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:47:30
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'participant called today to report that he Junlin Long (b) (4) had been hospitalized from November 29th to December 2nd, 2020, due to 6 episodes of vomiting and loss of consciousness.'	(b) (4)	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User entered 'I'	System	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User entered 'I'	System	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:23:00
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:49
User entered '0'	System	02 Dec 2020 19:36:48

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:31
User entered 'USA-US085-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	03 Dec 2020 15:07:28

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:48:34
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'this subject was not assessed for potential COVID-19 infection.' (Site from DM).	Junlin Long (b) (4) (b) (4)	15 Feb 2021 17:35:22
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:09:57
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:53
Data point term sent to Coder	System	02 Dec 2020 19:38:28
User entered 'nausea'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:00:41
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 19:41:40
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 19:37:46
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '3 Dec 2020' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:00:41
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 19:41:40
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Dec 2020 19:41:40
User entered empty; reason for change Data Entry Error	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:41:40
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 19:37:46
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '2 Dec 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'conmed updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Junlin Long (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 15:32:21 26 Jan 2021 19:41:24 14 Jan 2021 07:17:47 15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:47:13
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4)	23 Feb 2021 20:09:03
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:00:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:22:10
Query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' answered with 'participant signed ama, so etiology cannot be obtained.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:53:38
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:48:14
User entered 'PARTICIPANT CALLED TODAY TO REPORT THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:48:14
update: Patient presented to the ER on 12/01/2020 with right lower quadrant abdominal pain that was present x 2 days. In addition, he reported several episodes of vomiting, and loss of consciousness. He underwent a CT scan of the abdomen and pelvis W/WO contrast which revealed multiple areas of attenuation consistent with liver cysts. Chest X-ray which was normal and an US of the liver which revealed multiple cysts with the largest measuring 1.8cm. Labs revealed total bilirubin was above normal limits at 1.40 mg/dl. He was admitted for further evaluation. The patient left the hospital AMA on 12/02/2020.' reason for change: New Information		
User opened query 'PV Query - Please provide the etiology of the abdominal pain, nausea, vomiting and loss of consciousness. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:48:12
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'participant called today to report that he had been hospitalized from November 29th to December 2nd, 2020, due to 6 episodes of vomiting and loss of consciousness.'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:37:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 19:37:46

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Flatulence, LLT: Gas - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:38:53
Data point term sent to Coder	System	02 Dec 2020 19:38:28
User entered 'gas'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User entered empty.	System	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:01:28
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '3 Dec 2020' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:01:28
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User entered empty.	System	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Un-verified.	(b) (4)	02 Feb 2021 17:45:40
User entered '1' reason for change: Per Query Resolution	Junlin Long (b) (4)	02 Feb 2021 17:45:40
DataPoint Verified.	(b) (4)	15 Dec 2020 15:58:54
User entered '0' reason for change: Data Entry Error	Junlin Long (b) (4)	07 Dec 2020 19:58:33
User entered '1'	Junlin Long (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:25:57
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:45:47
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:45:40
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:45:40
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	14 Jan 2021 07:17:58
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '1' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	07 Dec 2020 19:58:33
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:47:25
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 20:09:15
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:36:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:01:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User entered '0'	System	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27
User entered 'I'	System	02 Dec 2020 19:38:19

US3622116

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:23:27

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:40:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 19:40:10
Data point term sent to Coder	System	02 Dec 2020 19:39:29
User entered 'constipation'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User entered empty.	System	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:02:11
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '3 Dec 2020' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:02:11
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User entered empty.	System	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	03 Dec 2020 16:02:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User entered '0'	System	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07
User entered 'I'	System	02 Dec 2020 19:39:28

US3622116

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:25:07

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:05:55
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:04:57
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:04:57
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 20:04:57
	(b) (4), (b) (6)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	29 Apr 2021 20:04:57
	(b) (4), (b) (6)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 19:12:02
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	08 Dec 2020 19:11:58
'USA-US085-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User closed query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:26:38
Query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'participant signed ama; unable to obtain final information to confirm if the cyst was benign or cancerous' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:55:42
User opened query 'Per DM CLR: Please update the condition to confirm if the Cyst was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:11:04
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic and hepatobiliary disorders NEC, PT: Hepatic cyst, LLT: Hepatic cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:04:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 20:04:50
Data point term sent to Coder	System	07 Dec 2020 20:03:33
User entered 'liver cyst'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 10:46:48
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' answered with 'It's still ongoing. Event end date will be provided once it's available.' (Site from DM).	Junlin Long (b) (4)	26 Apr 2021 12:47:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 18:55:00
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:30:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' answered with 'According to records, this SAE is still ongoing.' (Site from Safety).	Junlin Long (b) (4)	28 Apr 2021 20:55:27
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:04:54
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:04:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available, for liver cyst. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:35:14
User entered empty.	System	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4)	29 Apr 2021 12:56:21
reason for change: New Information	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered '0' reason for change: New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '1'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered empty; reason for change New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '29 Nov 2020'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered empty; reason for change New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '2 Dec 2020'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered empty; reason for change New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'No (N)'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered 'I'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:47:48
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4)	23 Feb 2021 20:09:28
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:37:08
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome for liver cyst, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:35:08
Query 'PV Query: Please provide the final event outcome for liver cyst, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'participant signed ama; unable to obtain final outcome for liver cyst' (Site from Safety).	Junlin Long (b) (4)	02 Feb 2021 17:56:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
User opened query 'PV Query: Please provide the final event outcome for liver cyst, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:35:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	07 Dec 2020 20:02:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:54
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
User entered empty; reason for change New Information	Junlin Long (b) (4)	29 Apr 2021 12:56:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 15:35:38
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records sent' (Site from Safety).	Junlin Long (b) (4)	02 Feb 2021 17:47:42
	(b) (4)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:43:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'narrative updated' (Site from Safety).	Junlin Long (b) (4)	29 Jan 2021 19:45:53
	(b) (4)	
DataPoint Un-verified.	Junlin Long (b) (4)	29 Jan 2021 19:45:30
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT REPORTED THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS. DURING HOSPITALIZATION, PARTICIPANT WAS DIAGNOSED WITH LIVER CYST. update: Patient presented to the ER on 12/01/2020 with right lower quadrant abdominal pain that was present x 2 days. In addition, he reported several episodes of vomiting, and loss of consciousness. He underwent a CT scan of the abdomen and pelvis W/WO contrast which revealed multiple areas of attenuation consistent with liver cysts. Chest X-ray which was normal and an US of the liver which revealed multiple cysts with the largest measuring 1.8cm. Labs revealed total bilirubin was above normal limits at 1.40 mg/dl. He was admitted for further evaluation. The patient left the hospital AMA on 12/02/2020.' reason for change: New Information	Junlin Long (b) (4) (b) (4)	29 Jan 2021 19:45:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:37:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'based on medical records, participant was tested covid-19 negative on December 1, 2020.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:44:50
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:43:07

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:42:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:42:08
User closed query 'PV Query: Were the events of vomiting, nausea, loss of consciousness, and right upper quadrant abdominal pain, symptoms of the liver cyst? If so, please consider deleting any symptoms.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 18:51:22
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:54
Query 'PV Query: Were the events of vomiting, nausea, loss of consciousness, and right upper quadrant abdominal pain, symptoms of the liver cyst? If so, please consider deleting any symptoms.' answered with 'according to this participant's medical records, the events were not symptoms of the liver cyst.' (Site from Safety).	Junlin Long (b) (4)	14 Dec 2020 17:51:42
User opened query 'PV Query: Were the events of vomiting, nausea, loss of consciousness, and right upper quadrant abdominal pain, symptoms of the liver cyst? If so, please consider deleting any symptoms.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 16:35:56
User entered 'PARTICIPANT REPORTED THAT HE HAD BEEN HOSPITALIZED FROM NOVEMBER 29TH TO DECEMBER 2ND, 2020, DUE TO 6 EPISODES OF VOMITING AND LOSS OF CONSCIOUSNESS. during hospitalization, participant was diagnosed with liver cyst.'	Junlin Long (b) (4)	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 12:56:21
User entered '1'	System	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 20:02:33

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	26 Jan 2021 19:14:55
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	26 Jan 2021 19:14:55
Data point term sent to Coders	System	26 Jan 2021 19:13:46
User entered 'gerd'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '1 Dec 2020'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
User entered empty.	System	26 Jan 2021 19:13:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '1 Dec 2020'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
User entered empty.	System	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Junlin Long	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'l'	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User closed query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:47:59
Query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'reported procedures were diagnostic procedures. they were not procedures for treatments.' (Site from DM).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 20:09:38
User opened query 'Per DM CLR: Please review if ConProc should also be added as there is a procedure that matches this AE within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:37:46
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:02:26
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Jan 2021 19:13:40
	(b) (4)	

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:35:48
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
User entered '0'	System	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27
User entered '1'	System	26 Jan 2021 19:13:40

US3622116

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:10:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:22:27

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:10:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:16
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:00:22
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:56:29

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 20:59:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 20:59:46
Data point term sent to Coder	System	09 Sep 2020 20:58:56
User entered 'multivitamins'	(b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 20:58:37

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:01:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:01:42
Data point term sent to Coder	System	09 Sep 2020 21:01:04
User entered 'omega 3'	(b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:25:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 21:00:45

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 16:42:25
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 Sep 2020 16:42:25
Data point term sent to Coder	System	30 Sep 2020 16:37:59
User entered 'vitamin d3'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'supplement vitamin'	Junlin Long (b) (4)	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 03:10:16
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dosage unknown; updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:50:45
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:50:26
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:50:26
User entered 'unknown' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:50:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:36:55
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 12:06:12
User entered '1'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:50:26
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:50:26
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Per Query Resolution	Junlin Long (b) (4)	24 Feb 2021 12:50:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
	(b) (4)	
User entered 'capsule (CAPSULE)'	Junlin Long (b) (4)	30 Sep 2020 16:37:54
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:50:26
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:50:26
User entered 'unknown' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:50:26
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	30 Sep 2020 16:37:54
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'three times daily (TID)'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Oral (ORAL)'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'un UNK 2019'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:37:54

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:30:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:30:26
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 12:06:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN-C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:44:32
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 Sep 2020 16:44:32
Data point term sent to Coder	System	30 Sep 2020 16:39:02
User entered 'vitamin c'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'supplement vitamin'	Junlin Long (b) (4)	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 03:10:56
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dosage unknown; updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:51:17
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:51:10
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:51:10
User entered 'unknown' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	24 Feb 2021 12:51:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:36:41
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 12:06:12
User entered '1'	Junlin Long (b) (4) (b) (4)	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:51:10
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:51:10
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Per Query Resolution	Junlin Long (b) (4)	24 Feb 2021 12:51:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
	(b) (4)	
User entered 'tablet (TABLET)'	Junlin Long (b) (4)	30 Sep 2020 16:38:20
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:51:10
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:51:10
User entered 'unknown' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	24 Feb 2021 12:51:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	30 Sep 2020 16:38:20
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'once daily (QD)'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Oral (ORAL)'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'un UNK 2019'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered '0'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'Yes (Y)'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered empty.	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 12:06:12
User entered 'No (N)'	Junlin Long	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:38:20

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PITAVASTATIN CALCIUM, PRODUCTSYNONYM: LIVALO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Oct 2020 14:50:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 14:50:50
Data point term sent to Coder	System	26 Oct 2020 14:14:51
User entered 'livalo'	Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'hypercholesterolemia'	Junlin Long (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '10'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'mg (mg)'	Junlin Long (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Oct 2020 14:14:50
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'once daily (QD)'	Junlin Long (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Oct 2020 14:14:50
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Oct 2020 14:14:50
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '15 Sep 2020'	Junlin Long (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:24:52
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:24:52
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:24:52
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 14:14:50
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:24:52
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	04 Mar 2021 18:24:52
User entered '12 Jan 2021' reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	26 Oct 2020 14:14:50
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
User entered '1'	System	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
User entered '1'	System	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:53
User entered '804 (804)'	System	26 Oct 2020 14:14:50

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
User closed query 'Source also indicates that the subject received the following medications: Morphine, Zofran, Pepesd (sic), Iopamidol. Please clarify' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 13:45:30
Query 'Source also indicates that the subject received the following medications: Morphine, Zofran, Pepesd (sic), Iopamidol. Please clarify' answered with 'conmed updated' (Site from CRA).	Junlin Long (b) (4)	02 Feb 2021 17:40:39
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User opened query 'Source also indicates that the subject received the following medications: Morphine, Zofran, Pepesd (sic), Iopamidol. Please clarify' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 16:03:26
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
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.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Oct 2020 16:58:31
Data point term sent to Coder	(b) (4)	
User entered 'seasonal flu vaccine'	System	26 Oct 2020 14:15:53
	Junlin Long (b) (4)	26 Oct 2020 14:15:34
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'prophylaxis for flu'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'l'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Other (OTHER)'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'injection'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'once (ONCE)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Oct 2020 14:15:34
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	26 Oct 2020 14:15:34
	(b) (4)	

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '25 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered '25 Oct 2020'	Junlin Long (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:03:40
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:21:56
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
User entered empty.	System	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
User entered empty.	System	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:57
User entered empty.	System	26 Oct 2020 14:15:34

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:28:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:28:56
Data point term sent to Coder	System	26 Jan 2021 18:58:12
User entered 'morphine'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'abdominal pain (right lower quadrant)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '4'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User entered empty.	System	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User entered empty.	System	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:04
User entered empty.	System	26 Jan 2021 18:57:44

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:00:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:00:50
Data point term sent to Coder	System	26 Jan 2021 19:00:14
User entered 'zofran'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'nausea, vomiting'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '4'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User entered empty.	System	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User entered empty.	System	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:08
User entered empty.	System	26 Jan 2021 18:59:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:12:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:12:01
Data point term sent to Coder	System	26 Jan 2021 19:10:28
User entered 'Famotidine' reason for change: New Information	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:09:53
Data point term sent to Coder	System	26 Jan 2021 19:05:21
User entered 'pepcid'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'gerd'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '20'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User entered empty.	System	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User entered empty.	System	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:13
User entered empty.	System	26 Jan 2021 19:05:21

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
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: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 12:38:09
Data point term sent to Coder	System	26 Jan 2021 19:12:45
User entered 'iopamidol'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'radiopaque contrast agent'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '50'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'mL (mL)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'once (ONCE)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 03:59:22
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'according to medical records from hospital, route of administration of this medication was oral.' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Mar 2021 15:34:19
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:57:24
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered '1 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:45:36
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User entered empty.	System	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User entered empty.	System	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:22
User entered empty.	System	26 Jan 2021 19:12:23

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 18:27:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 18:27:02
Data point term sent to Coder	System	04 Mar 2021 18:26:29
User entered 'atorvastatin'	Junlin Long (b) (4) (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'No (N)'	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'hypercholesterolemia'	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered '40'	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'mg (mg)'	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered empty.	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'once daily (QD)'	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered empty.	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'Oral (ORAL)'	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered empty.	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered '19 Jan 2021'	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered '0'	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered empty.	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:54
User entered 'No (N)'	Junlin Long	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 18:26:18

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:33:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:33:39
Data point term sent to Coder	System	06 Apr 2021 14:45:33
Coding entries removed.	(b) (4), (b) (6)	06 Apr 2021 14:44:55
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:16:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:16:31
Data point term sent to Coder	System	23 Mar 2021 19:00:54
User entered 'percocet'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:54:29
User closed query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:45:32
Query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:45:06
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 14:44:55
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 14:44:55
User entered 'Abdominal hernia repair' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:44:55
User opened query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:57:22
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'post-surgery pain'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:54:29
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (325/5). Please correct the dosage or provide comment for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:45:10
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (325/5). Please correct the dosage or provide comment for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:45:15
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 14:44:55
User entered '325/5' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 14:44:55
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication (325/5). Please correct the dosage or provide comment for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:01:23
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Mar 2021 16:09:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 16:09:54
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	30 Mar 2021 16:09:54
User entered '3.5/5' reason for change: New Information	Junlin Long (b) (4) (b) (4)	30 Mar 2021 16:09:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:00:05
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Mar 2021 16:09:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 16:09:54
DataPoint Un-verified.	Junlin Long (b) (4)	30 Mar 2021 16:09:54
User entered 'mg (mg)' reason for change: New Information	(b) (4)	30 Mar 2021 16:09:54
DataPoint Verified.	Junlin Long (b) (4)	30 Mar 2021 16:09:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:00:05
	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'four times daily (QID)'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '16 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '18 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User entered '4'	System	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User entered '1'	System	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:30
User entered '804 (804)'	System	23 Mar 2021 19:00:05

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:08:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:08:30
Data point term sent to Coder	System	06 Apr 2021 14:44:32
Coding entries removed.	(b) (4), (b) (6)	06 Apr 2021 14:44:32
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	01 Apr 2021 18:13:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:12:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:07
Data point term sent to Coder	System	23 Mar 2021 19:01:55
User entered 'celebrex'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:54:29
User closed query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:48:01
Query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:44:38
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 14:44:32
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 14:44:32
User entered 'Abdominal hernia repair ' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Apr 2021 14:44:32
User opened query 'Per DM CLR: Please note that there is no AE or ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:57:10
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'post-surgery pain'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '400'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '16 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered '22 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:07
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User entered '1'	System	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User entered '1'	System	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:10:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:18:34
User entered '804 (804)'	System	23 Mar 2021 19:01:06

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:10:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:27
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Yes (Y)'	Junlin Long (b) (4)	02 Feb 2021 17:47:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	26 Jan 2021 19:21:05
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	15 Dec 2020 16:04:03

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '1 Dec 2020'	Junlin Long (b) (4)	02 Feb 2021 17:48:36

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'chest x-ray'	Junlin Long	02 Feb 2021 17:48:36

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	02 Feb 2021 17:48:36

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:10:42

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	Junlin Long	02 Feb 2021 17:48:36

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '1 Dec 2020'	Junlin Long (b) (4)	02 Feb 2021 17:50:35

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'ct abdomen and pelvis with and without contrast'	Junlin Long (b) (4)	02 Feb 2021 17:50:35

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	02 Feb 2021 17:50:35

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:10:42

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	02 Feb 2021 17:50:35
	(b) (4)	

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '1 Dec 2020'	Junlin Long (b) (4)	02 Feb 2021 17:51:06

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'liver ultrasound'	Junlin Long (b) (4)	02 Feb 2021 17:51:06

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	02 Feb 2021 17:51:06

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:10:42

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered empty.	Junlin Long (b) (4)	02 Feb 2021 17:51:06

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered '22 Feb 2021'	Junlin Long (b) (4)	04 Mar 2021 18:30:18

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'colonoscopy'	Junlin Long (b) (4)	04 Mar 2021 18:30:18

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	04 Mar 2021 18:30:18

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:10:42

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:08
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:36:37
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:53:55
User entered empty.	Junlin Long (b) (4)	04 Mar 2021 18:30:18

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:12
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:13:59
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:47:35
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 11:47:35
User entered '16 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 11:47:35
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:37
User entered '23 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 18:55:39

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:37
User entered 'abdominal hernia repair'	(b) (4), (b) (6)	23 Mar 2021 18:55:39

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:12
User closed query 'Per CDM, DM CLR RQ: Please note that MH #3 of ABDOMINAL HERNIA has an end date (16 Mar 2021) which is prior to the date of this procedure 23 Mar 2021. Please review and reconcile as appropriate, otherwise provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Susanne Doblecki-Lewis	05 Apr 2021 04:09:04 01 Apr 2021 18:13:59
Query 'Per CDM, DM CLR RQ: Please note that MH #3 of ABDOMINAL HERNIA has an end date (16 Mar 2021) which is prior to the date of this procedure 23 Mar 2021. Please review and reconcile as appropriate, otherwise provide clarification. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:47:59
User opened query 'Per CDM, DM CLR RQ: Please note that MH #3 of ABDOMINAL HERNIA has an end date (16 Mar 2021) which is prior to the date of this procedure 23 Mar 2021. Please review and reconcile as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:27:38
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:27:38
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated. Refer to MH' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:23:08
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 13:22:34
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 13:22:34
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 13:22:34

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:42

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:24:07
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:37
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 18:58:36
User entered 'Medical History (MH)'	(b) (4), (b) (6)	23 Mar 2021 18:55:39

US3622116

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:10:42

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:12
User signature succeeded.	Susanne Doblecki-Lewis	26 Mar 2021 20:09:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:36:37
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 18:55:39

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
User entered '03/Dec/2020 15:07'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
User entered '04/Dec/2020 13:18'	System	04 Dec 2020 13:18:29

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 19:12:25
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 13:18:29

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
User entered '08/Dec/2020 19:12'	System	08 Dec 2020 19:12:38

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 16:42:08
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 19:12:38

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered '15/Dec/2020 12:51'	(b) (4) System	15 Dec 2020 18:52:00

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 16:42:08
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:52:00

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
User entered '27/Jan/2021 11:41'	(b) (4) System	27 Jan 2021 16:41:42

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 16:42:08
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 16:41:42

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '01/Feb/2021 13:50'	(b) (4) System	01 Feb 2021 13:50:49

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 15:47:03
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 13:50:49

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
User entered '03/Feb/2021 10:46'	(b) (4) System	03 Feb 2021 15:46:58

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:32:49
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 15:47:03
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 15:46:58

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
User entered '29/Apr/2021 12:31'	System	29 Apr 2021 16:31:26

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:26

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'USA-US085-2020-MRNA-1273-P301000003'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Yes (Y)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'No (N)'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Susanne'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Doblecki-Lewis'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '1120 NW 14th Street'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'Miami'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered 'FL'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 15:07:47
User entered '33136'	System	03 Dec 2020 15:06:24

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:36
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:50:33
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:58:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 13:18:18
User entered 'US'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:10:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	29 Apr 2021 20:09:27
User entered '8'	System	29 Apr 2021 16:31:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:02:26
	(b) (4)	
User entered '7'	System	03 Feb 2021 15:46:58
Signature has been broken.	System	01 Feb 2021 13:50:49
User entered '6'	System	01 Feb 2021 13:50:49
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:06:20
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 16:41:42
User entered '5'	System	27 Jan 2021 16:41:42
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:02:54
	(b) (4)	
User entered '4'	System	15 Dec 2020 18:52:00
User entered '3'	System	08 Dec 2020 19:12:38
User entered '2'	System	04 Dec 2020 13:18:29
User entered '1'	System	03 Dec 2020 15:07:56

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:10:42

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
	(b) (4)	
User entered '29/Apr/2021 16:09'	System	29 Apr 2021 20:09:27

US3622116

Folder: SAE USA-US085-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	30 Apr 2021 16:05:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:09:27