

US3622211 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:09:10

All time stamps listed in this document are displayed in GMT

US3622211

**Form: Participant Creation**

**Data signed:** (b) (4) 26 Sep 2020 13:14:22

**Generated On: 10 Jun 2021 09:09:10**

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[Participant ID](#)

US3622211

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

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US3622211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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

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US3622211

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
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

US3622211

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version  
Amendment 1   
Amendment 2   
Amendment 3   
Amendment 4   
Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail  
Withdrew Consent   
Inclusion/Exclusion   
Cohort Full   
Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3622211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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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) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:32 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:32
Height ( <i>xxx.x</i> )	70.5 in
Weight ( <i>xxx.x</i> )	137 lb
BMI ( <i>xxx.x</i> )	19.42013 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3622211

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

21 SEP 2020

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

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US3622211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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**Occupational Risk**

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**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

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**Specify**

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**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) 26 Sep 2020 13:14:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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

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US3622211

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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

What was the participant's randomization number? 114867

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) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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 ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:32 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:32
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

Height	ND - Not Done
Weight	ND - Not Done
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 ( <i>dd MMM yyyy</i> )	21 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:31 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 13:31
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	77 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	95 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy) \_\_\_\_\_

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

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US3622211

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:57 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:57

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) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 21 SEP 2020

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Collection time (*00:00-23:59*) 12:00 (24 HR)

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Collection date and time (derived) 21 SEP 2020 12:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Collection date ( <i>dd MMM yyyy</i> )			21 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:04	21 SEP 2020 12:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.7 °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 21 SEP 2020 13:33  
PC Open Date & Time 21 SEP 2020 13:17  
PC Close Date & Time 21 SEP 2020 15:47

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**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** 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 21 SEP 2020 18:54  
PC Open Date & Time 21 SEP 2020 16:42  
PC Close Date & Time 22 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 SEP 2020 13:26
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 12:24
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 SEP 2020 12:24
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE in °F</b>	97.2 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 SEP 2020 14:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 22:18
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 13:35

PC Open Date & Time

21 SEP 2020 13:17

PC Close Date & Time

21 SEP 2020 15:47

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 18:54

PC Open Date & Time

21 SEP 2020 16:42

PC Close Date & Time

22 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 2

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

22 SEP 2020 13:27

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 3

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

23 SEP 2020 12:24

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 4

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

24 SEP 2020 12:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	25 SEP 2020 12:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 6

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

26 SEP 2020 14:06

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 7

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

27 SEP 2020 22:19

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

No   
Yes

---

PC Time stamp	21 SEP 2020 13:35
PC Open Date & Time	21 SEP 2020 13:17
PC Close Date & Time	21 SEP 2020 15:47

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

No

Yes

---

PC Time stamp	21 SEP 2020 18:55
PC Open Date & Time	21 SEP 2020 16:42
PC Close Date & Time	22 SEP 2020 11:59

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 13:27
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 12:25
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

---

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

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 12:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 14:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

---

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 22:19
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

---

US3622211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:06:36

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:06:36

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:06:36

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:06:36

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 20:10:56

Generated On: 10 Jun 2021 09:09:10

---

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*

---

US3622211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:10:56

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 OCT 2020

---

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

---

Folder OID VISIT2

---

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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 ( <i>dd MMM yyyy</i> )	19 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:37 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:37
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> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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 ( <i>dd MMM yyyy</i> )	19 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:25 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 13:25
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	87 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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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.*

---

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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) 19 OCT 2020

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 19 OCT 2020 12:51

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

US3622211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	19 OCT 2020
Collection time ( <i>00:00-23:59</i> )	12:00 (24 HR)
Collection date and time (derived)	19 OCT 2020 12:00

---

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

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Collection date ( <i>dd MMM yyyy</i> )			19 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:53	19 OCT 2020 11:53
Nasopharyngeal Swab 2	No		

---

US3622211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:06:14

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.2 °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 19 OCT 2020 13:32

PC Open Date & Time 19 OCT 2020 13:11

PC Close Date & Time 19 OCT 2020 15:41

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**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 19 OCT 2020 16:44  
PC Open Date & Time 19 OCT 2020 16:36  
PC Close Date & Time 20 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 OCT 2020 14:04
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 OCT 2020 18:55
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**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 97.8 °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 22 OCT 2020 18:28

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 OCT 2020 13:28
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes   
No

Please record your **TEMPERATURE** in °F \_\_\_\_\_  
Was any **MEDICATION TAKEN** today for pain or fever? Yes   
No

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred \_\_\_\_\_  
To **PREVENT** pain or fever from occurring \_\_\_\_\_  
PC Time Stamp \_\_\_\_\_  
PC Open Date & Time 24 OCT 2020 12:00  
PC Close Date & Time 25 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 OCT 2020 10:44
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

19 OCT 2020 13:32

PC Open Date & Time

19 OCT 2020 13:11

PC Close Date & Time

19 OCT 2020 15:41

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**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

19 OCT 2020 16:44

PC Open Date & Time

19 OCT 2020 16:36

PC Close Date & Time

20 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	20 OCT 2020 14:05
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	21 OCT 2020 18:56
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 4

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

22 OCT 2020 18:28

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 5

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

23 OCT 2020 13:29

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 6

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

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 7

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

26 OCT 2020 10:45

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

No

Yes

---

PC Time stamp	19 OCT 2020 13:33
PC Open Date & Time	19 OCT 2020 13:11
PC Close Date & Time	19 OCT 2020 15:41

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

No

Yes

---

PC Time stamp	19 OCT 2020 16:45
PC Open Date & Time	19 OCT 2020 16:36
PC Close Date & Time	20 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 14:05
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 18:56
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	22 OCT 2020 18:29
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 13:29
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

Yes

---

PC Time stamp

---

PC Open Date & Time

24 OCT 2020 12:00

---

PC Close Date & Time

25 OCT 2020 11:59

---

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**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

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

---

	Yes <input type="checkbox"/>
PC Time stamp	26 OCT 2020 10:45
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

---

US3622211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:38:56

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 OCT 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3622211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:38:56

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:38:56

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted?

Yes

No

---

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

2 NOV 2020

---

Please select one status for the follow-up contact

Contact Made

Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:38:56

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Nov 2020 19:08:21

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3622211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 19:08:21

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 NOV 2020

---

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

---

Folder OID VISIT3

---

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	11:56 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 11:56
Temperature ( <i>xxx.x</i> )	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	54 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 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> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

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.*

---

US3622211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 16 NOV 2020

---

Collection time (*00:00-23:59*) 12:20 (24 HR)

---

Collection date and time (derived) 16 NOV 2020 12:20

---

US3622211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 61

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

---

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 68

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

No

Yes

Have you been exposed to someone with known SARS-CoV-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 19:09:53

Patient Cloud Open Date & Time 25 NOV 2020 00:01

Patient Cloud Close Date & Time 29 NOV 2020 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 12:03:23
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

Yes

Have you been exposed to someone with known SARS-CoV-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 00:20:09

Patient Cloud Open Date & Time 09 DEC 2020 00:01

Patient Cloud Close Date & Time 13 DEC 2020 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 DEC 2020 17:43:07
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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	23 DEC 2020 02:37:33
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 30 DEC 2020 18:01:01

Patient Cloud Open Date & Time 30 DEC 2020 00:01

Patient Cloud Close Date & Time 03 JAN 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 JAN 2021 08:54:00
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <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	13 JAN 2021 20:30:58
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 JAN 2021 11:39:59
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 131

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 27 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#) 31 JAN 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 03:15:20
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 11 FEB 2021 08:28:34

Patient Cloud Open Date & Time 10 FEB 2021 00:01

Patient Cloud Close Date & Time 14 FEB 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 17 FEB 2021 10:50:25

Patient Cloud Open Date & Time 17 FEB 2021 00:01

Patient Cloud Close Date & Time 21 FEB 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 26 FEB 2021 20:31:46

Patient Cloud Open Date & Time 24 FEB 2021 00:01

Patient Cloud Close Date & Time 28 FEB 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <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	03 MAR 2021 22:42:19
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <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	10 MAR 2021 00:38:04
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 18 MAR 2021 06:24:55

Patient Cloud Open Date & Time 17 MAR 2021 00:01

Patient Cloud Close Date & Time 21 MAR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 MAR 2021 00:02:39
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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 31 MAR 2021 01:39:35

Patient Cloud Open Date & Time 31 MAR 2021 00:01

Patient Cloud Close Date & Time 04 APR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 APR 2021 00:16:04
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <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	14 APR 2021 00:29:33
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 <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	21 APR 2021 12:47:27
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 APR 2021 22:26:06
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 229

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 MAY 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAY 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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  Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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

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Date and time of submission

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[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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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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  Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 29 AUG 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

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Folder: New Safety Follow Up Diary (1)

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**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 404

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 31 OCT 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 NOV 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 05 DEC 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 15 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 19 DEC 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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  Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 467

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 FEB 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 MAR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 MAR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 MAR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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  Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 670

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

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US3622211

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**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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US3622211

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**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 AUG 2022 23:59

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US3622211

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Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

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**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 SEP 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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   
Yes

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

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 NOV 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 NOV 2022 23:59

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US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2022 23:59

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US3622211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:09:10

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		02 MAR 2021 22:28:16

US3622211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 15:12:45

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 20 JAN 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3622211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:12:45

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:41:19

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 APR 2021

---

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

---

Folder OID VISIT4

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:41:19

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	12:46 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 12:46
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	92 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3622211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:41:19

Generated On: 10 Jun 2021 09:09:10

---

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.*

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:41:19

Generated On: 10 Jun 2021 09:09:10

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 APR 2021

---

Collection time (*00:00-23:59*) 13:00 (24 HR)

---

Collection date and time (derived) 19 APR 2021 13:00

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:41:19

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3622211**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:09:10**

---

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* \_\_\_\_\_

---

US3622211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3622211

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:09:10

---

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"/>

---

US3622211

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:09:10

---

Generate Next COVID-19 Assessment

Yes

No

---

US3622211

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

Form: Visit Date

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3622211

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:15:48

Generated On: 10 Jun 2021 09:09:10

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

US3622211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Height	72 in
Weight	240 lb
BMI (xxx.x)	32.61791

---

US3622211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

Height	72 in
Weight	240 lb
BMI (xxx.x)	32.61791
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)	10:45 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:45
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

Height	72 in
Weight	240 lb
BMI (xxx.x)	32.61791
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)	12:14 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 12:14
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

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

Form: Physical Examination

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

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.*

---

US3622211

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

Form: Exposure

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

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) 11:43 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 11:43

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

US3622211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00-23:59*) 10:54 (24 HR)

---

Collection date and time (derived) 19 JAN 2021 10:54

---

US3622211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00 - 23:59*) 10:57

---

Collection Date and Time (derived) 19 JAN 2021 10:57

---

US3622211

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

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

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* \_\_\_\_\_

---

US3622211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

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

---

US3622211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 15 FEB 2021

---

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

---

Folder OID OLD29

---

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

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 ( <i>dd MMM yyyy</i> )	15 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	11:44 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:44
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	90 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

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 ( <i>dd MMM yyyy</i> )	15 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	12:58 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:58
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	88 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG

US3622211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

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.*

---

US3622211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

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) 15 FEB 2021

What was the treatment time? (00:00-23:59) 12:26 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 12:26

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

US3622211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:16:33

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3622211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3622211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 15 MAR 2021

---

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

---

Folder OID OLD57

---

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:48 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 11:48
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	94 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3622211

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

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.*

---

US3622211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 15 MAR 2021

---

Collection time (*00:00-23:59*) 11:55 (24 HR)

---

Collection date and time (derived) 15 MAR 2021 11:55

---

US3622211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Jan 2021 15:09:15

Generated On: 10 Jun 2021 09:09:10

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID

Adverse event

HYPERCHOLESTEROLEMIA

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)

1 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

11 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

344 of 2394

EAB) (1725)

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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)	_____

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID USA-US085-2021-MRNA-1273-P30  
1000001

Adverse event ENCEPHALOPATHY

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) 1 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 2 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 1 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 2 JAN 2021

Admitted to ICU? Yes   
No   
Unknown

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 2394

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None True

---

Concomitant Medication False

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

---

Narrative \_\_\_\_\_

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

PARTICIPANT CALLED TO REPORT THAT ON 1/1/2021, THEY DEVELOPED ALTERED MENTAL STATUS AND WERE ADMITTED AT BAPTIST WEST KENDALL FOR A 24-HOUR OBSERVATION. ALL TESTING WAS NEGATIVE AND PATIENT REPORTS SYMPTOMS RESOLVED AND THEY WERE DISCHARGED ON 1/2/2021 AT 5:00 P.M. THEY WERE STARTED ON ASPIRIN 81 MG AND ATORVASTATIN 20 MG DAILY.

UPDATE: THE PARTICIPANT WENT TO THE ER ON 01/01/2021 FOR CONFUSION. PER HOSPITAL MEDICAL RECORDS HIS CONFUSION LASTED ABOUT 1 HOUR. HE WAS DISCHARGED ON 01/02/2021. PER HOSPITAL RECORDS BRAIN MRI ON 01/02/2021 REVEALED A 2CM ARACHNOID CYST AND RIGHT MASTOIDITIS. CHEST X-RAY ON 01/01/2021 REVEALED PERIPHERAL INTERSTITIAL INFILTRATES. HEAD MRA, CHEST CT, AND CT BRAIN WERE ALL NEGATIVE. EKG ON 01/01/2021 REVEALED SINUS TACHYCARDIA. ECHOCARDIOGRAM ON

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

---

01/02/2021 REVEALED GRADE 1  
DIASTOLIC DYSFUNCTION.  
CAROTID DUPLEX ON  
01/02/2021 WAS NORMAL. THE  
PATIENT'S CONFUSION FULLY  
RECOVERED, AND HE WAS  
DISCHARGED ON 01/02/2021.  
DISCHARGE DIAGNOSES WERE  
ENCEPHALOPATHY, BRAIN TIA  
PRESUMED, TRANSIENT  
GLOBAL AMNESIA PRESUMED,  
ARACHNOID CYST, RIGHT SIDE  
MASTOIDITIS, HYPERTENSION,  
GRADE 1 DIASTOLIC  
DYSFUNCTION, PERIPHERAL  
INFILTRATES, AND SINUS  
TACHYCARDIA.

---

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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US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID

Adverse event

BRAIN TIA PRESUMED

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)

1 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

2 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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EAB) (1725)

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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)	0

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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	
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 (6)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID	
Adverse event	BENIGN ARACHNOID CYST
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (6)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID

Adverse event

RIGHT SIDE MASTOIDITIS

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)

1 JAN 2021

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 (7)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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)	_____

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID \_\_\_\_\_

Adverse event \_\_\_\_\_ HYPERTENSION

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) \_\_\_\_\_ 1 JAN 2021

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 (8)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID

Adverse event

GRADE 1 DIASTOLIC  
DYSFUNCTION

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)

1 JAN 2021

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID	
Adverse event	PERIPHERAL INTERSTITIAL INFILTRATES
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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"/>

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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 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)	

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

AEID	
Adverse event	SINUS TACHYCARDIA
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (11)

Data signed: (b) (4) 19 Mar 2021 14:06:40

Generated On: 10 Jun 2021 09:09:10

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)	_____

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Sep 2020 13:14:22

Generated On: 10 Jun 2021 09:09:10

---

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

Yes

No

---

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

---

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication PROSCAR

Prophylaxis Yes   
No

Indication ENLARGE PROSTATE

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

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 APR 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 9 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication PREVENTION OF BLOOD CLOT

Dose per administration 81

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) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

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 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 11 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication ATORVASTATIN

Prophylaxis Yes   
No

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

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 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 11 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication DULCOLAX

Prophylaxis Yes   
No

Indication PREVENTION OF  
CONSTIPATION

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

	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 checked="" 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 JAN 2021
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy)	2 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

---

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

---

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication HEPARIN

Prophylaxis Yes   
No

Indication PREVENTION OF BLOOD CLOTS

Dose per administration 5000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNIT

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

If frequency is Other, specify EVERY 6 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

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 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 2 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication TRANDATE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

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 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 2 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication TRANDATE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

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 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 2 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication TRANDATE

Prophylaxis Yes   
No

Indication HYPERTENSION

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  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

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 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 2 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication MIRALAX

Prophylaxis Yes   
No

Indication PREVENTION OF  
CONSTIPATION

Dose per administration 17

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

	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 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 2 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

---

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

Name of Medication SENOKOT

Prophylaxis Yes   
No

Indication PREVENTION OF  
CONSTIPATION

Dose per administration 17.2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

---

	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 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 2 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Jan 2021 15:12:44

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 JAN 2021	BRAIN CT WO CONTRAST	Diagnostic	
1 JAN 2021	CT CHEST WO CONTRAST	Diagnostic	
2 JAN 2021	HEAD MRA WO CONTRAST	Diagnostic	
2 JAN 2021	BRAIN MRI WO CONTRAST	Diagnostic	
1 JAN 2021	CHEST SINGLE VIEW X-RAY	Diagnostic	
2 JAN 2021	ECHOCARDIOGRAM	Diagnostic	
1 JAN 2021	EKG	Diagnostic	
2 JAN 2021	CAROTID DUPLEX	Diagnostic	

US3622211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:09:10

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

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	11/JAN/2021 17:05
<b>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.</b>	<input checked="" type="checkbox"/> True

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	26/JAN/2021 15:56
<b>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.</b>	True

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	01/FEB/2021 17:06
<b>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.</b>	<input checked="" type="checkbox"/> True

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	09/FEB/2021 11:34
<b>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.</b>	True

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 21:59:01

Generated On: 10 Jun 2021 09:09:10

SAEID	USA-US085-2021-MRNA-1273-P301000001
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)	5
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:06
<b>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.</b>	True

Audit

US3622211 (Prod: University of Miami)

**US3622211**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:09:10**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'US3622211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:20:51

US3622211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:03

US3622211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:20:52

US3622211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:03

US3622211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'SCRN'	System	21 Sep 2020 17:06:03

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:20:53

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '56'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'YEARS'	System	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '56'	System	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:09:10

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:28

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'Sep 2020'	System	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '2020'	System	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:22

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:20:52

US3622211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:09:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '1'	System	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:09:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:04:46

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 19:23:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 19:23:44
Data point term sent to Coder	System	21 Sep 2020 19:23:00
User entered 'enlarged prostate'	(b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'Jan 2020'	System	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '2020'	System	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered empty.	System	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered empty.	System	21 Sep 2020 19:22:34

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '11:32'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '21 Sep 2020 11:32'	System	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '70.5' in	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05
DataPoint set to visible.	System	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '137' lb	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05
DataPoint set to visible.	System	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19.42013'	System	21 Sep 2020 19:19:05
DataPoint set to visible.	System	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'kg/m2'	System	21 Sep 2020 19:19:05
DataPoint set to visible.	System	21 Sep 2020 17:06:30

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered '98.6' F reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered 'Oral (Oral)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered '72' reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'bpm'	System	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered '18' reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'breaths/min'	System	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered '139' reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
Signature has been broken.	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User entered '91' reason for change: New Information	(b) (4) Junlin Long (b) (4)	18 Feb 2021 15:50:04
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	21 Sep 2020 19:19:05

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28

US3622211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28

US3622211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:12

US3622211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:19:12

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:09:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:25:17

US3622211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:45

US3622211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:45

US3622211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:06:45

US3622211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'VISIT1'	System	21 Sep 2020 17:06:45

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:25:28

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '114867'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:25:28

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 16:25:28

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46

US3622211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:09:10

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:46
DataPoint set to visible.	System	21 Sep 2020 17:06:22

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '11:32'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '21 Sep 2020 11:32'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '72'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'bpm'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'breaths/min'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '139'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '91'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '13:31'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '21 Sep 2020 13:31'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '77'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'bpm'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'breaths/min'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '149'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '95'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	21 Sep 2020 19:29:01

US3622211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:06

US3622211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:06

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

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 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '12:57'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '21 Sep 2020 12:57'	System	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'ONCE'	System	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 17:07:18

US3622211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:37

US3622211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:37

US3622211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '12:00'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:37

US3622211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 19:29:37

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '12:04'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '21 Sep 2020 12:04'	System	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered empty.	System	21 Sep 2020 19:29:58

US3622211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:30:03

US3622211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	21 Sep 2020 19:30:03

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:33:10', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6f1233d0-fcba-4cb7-8bdf-0f1b400c55b3'	System	21 Sep 2020 17:33:35
User entered 'Yes (Y)'	System	21 Sep 2020 17:33:35

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:33:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6f1233d0-fcba-4cb7-8bdf-0f1b400c55b3'	System	21 Sep 2020 17:33:35
User entered '98.7'	System	21 Sep 2020 17:33:35

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:33:22', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6f1233d0-fcba-4cb7-8bdf-0f1b400c55b3'	System	21 Sep 2020 17:33:35
User entered 'No (N)'	System	21 Sep 2020 17:33:35

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:33:28', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6f1233d0-fcba-4cb7-8bdf-0f1b400c55b3'	System	21 Sep 2020 17:33:35
User entered '21 Sep 2020 13:33'	System	21 Sep 2020 17:33:35

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 15:47'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:51:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '11b1b9ae-9fcb-4286-be11-f7d916309b6c'	System	21 Sep 2020 22:54:23
User entered 'Yes (Y)'	System	21 Sep 2020 22:54:23

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:17', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '11b1b9ae-9fcb-4286-be11-f7d916309b6c'	System	21 Sep 2020 22:54:23
User entered '96.7'	System	21 Sep 2020 22:54:23

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:53:33', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '11b1b9ae-9fcb-4286-be11-f7d916309b6c'	System	21 Sep 2020 22:54:23
User entered 'No (N)'	System	21 Sep 2020 22:54:23

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '11b1b9ae-9fcb-4286-be11-f7d916309b6c'	System	21 Sep 2020 22:54:23
User entered '21 Sep 2020 18:54'	System	21 Sep 2020 22:54:23

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 16:42'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 2'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:26:31', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4e221254-3e12-4d60-8991-6053c267e52d'	System	22 Sep 2020 17:26:58
User entered 'Yes (Y)'	System	22 Sep 2020 17:26:58

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:26:41', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4e221254-3e12-4d60-8991-6053c267e52d' User entered '96.6'	System	22 Sep 2020 17:26:58
	System	22 Sep 2020 17:26:58

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:26:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4e221254-3e12-4d60-8991-6053c267e52d'	System	22 Sep 2020 17:26:58
User entered 'No (N)'	System	22 Sep 2020 17:26:58

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:26:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4e221254-3e12-4d60-8991-6053c267e52d' User entered '22 Sep 2020 13:26'	System	22 Sep 2020 17:26:58
	System	22 Sep 2020 17:26:58

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 3'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:23:43', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '54c6ab41-b4ef-4652-b76b-cb76ccf87480'	System	23 Sep 2020 16:24:07
User entered 'Yes (Y)'	System	23 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:23:51', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '54c6ab41-b4ef-4652-b76b-cb76ccf87480'	System	23 Sep 2020 16:24:07
User entered '96.7'	System	23 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:23:56', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '54c6ab41-b4ef-4652-b76b-cb76ccf87480'	System	23 Sep 2020 16:24:07
User entered 'No (N)'	System	23 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:02', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '54c6ab41-b4ef-4652-b76b-cb76ccf87480'	System	23 Sep 2020 16:24:07
User entered '23 Sep 2020 12:24'	System	23 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 4'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:23:36', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'eb556828-a7f8-4f9a-966b-27b30c978167'	System	24 Sep 2020 16:24:07
User entered 'Yes (Y)'	System	24 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:23:51', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'eb556828-a7f8-4f9a-966b-27b30c978167'	System	24 Sep 2020 16:24:07
User entered '96.5'	System	24 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:23:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'eb556828-a7f8-4f9a-966b-27b30c978167'	System	24 Sep 2020 16:24:07
User entered 'No (N)'	System	24 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'eb556828-a7f8-4f9a-966b-27b30c978167'	System	24 Sep 2020 16:24:07
User entered '24 Sep 2020 12:24'	System	24 Sep 2020 16:24:07

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 5'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1f76a759-b2f1-45ac-bc69-42ae3c8801ef'	System	25 Sep 2020 16:03:01
User entered 'Yes (Y)'	System	25 Sep 2020 16:03:01

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1f76a759-b2f1-45ac-bc69-42ae3c8801ef'	System	25 Sep 2020 16:03:01
User entered '97.8'	System	25 Sep 2020 16:03:01

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1f76a759-b2f1-45ac-bc69-42ae3c8801ef'	System	25 Sep 2020 16:03:01
User entered 'No (N)'	System	25 Sep 2020 16:03:01

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1f76a759-b2f1-45ac-bc69-42ae3c8801ef'	System	25 Sep 2020 16:03:01
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 16:03:01

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 6'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:30', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f7f373c9-907c-4ad9-9a3d-89c9e2301406'	System	26 Sep 2020 18:05:49
User entered 'Yes (Y)'	System	26 Sep 2020 18:05:49

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:37', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f7f373c9-907c-4ad9-9a3d-89c9e2301406'	System	26 Sep 2020 18:05:49
User entered '97.2'	System	26 Sep 2020 18:05:49

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:42', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f7f373c9-907c-4ad9-9a3d-89c9e2301406'	System	26 Sep 2020 18:05:49
User entered 'No (N)'	System	26 Sep 2020 18:05:49

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:45', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f7f373c9-907c-4ad9-9a3d-89c9e2301406'	System	26 Sep 2020 18:05:49
User entered '26 Sep 2020 14:05'	System	26 Sep 2020 18:05:49

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 7'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:07', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a7dbbd00-887c-4aaf-9b39-373e5626f302'	System	28 Sep 2020 02:18:26
User entered 'Yes (Y)'	System	28 Sep 2020 02:18:26

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a7dbbd00-887c-4aaf-9b39-373e5626f302'	System	28 Sep 2020 02:18:26
User entered '97.6'	System	28 Sep 2020 02:18:26

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:17', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a7dbbd00-887c-4aaf-9b39-373e5626f302'	System	28 Sep 2020 02:18:26
User entered 'No (N)'	System	28 Sep 2020 02:18:26

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a7dbbd00-887c-4aaf-9b39-373e5626f302'	System	28 Sep 2020 02:18:26
User entered '27 Sep 2020 22:18'	System	28 Sep 2020 02:18:26

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:33:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fdbf3a4d-3067-415e-bbd9-476311144736'	System	21 Sep 2020 17:35:12
User entered 'None (1)'	System	21 Sep 2020 17:35:12

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:34:07', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fdbf3a4d-3067-415e-bbd9-476311144736'	System	21 Sep 2020 17:35:12
User entered 'No (N)'	System	21 Sep 2020 17:35:12

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:34:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fdbf3a4d-3067-415e-bbd9-476311144736'	System	21 Sep 2020 17:35:12
User entered 'No (N)'	System	21 Sep 2020 17:35:12

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:34:45', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fdbf3a4d-3067-415e-bbd9-476311144736'	System	21 Sep 2020 17:35:12
User entered 'None (1)'	System	21 Sep 2020 17:35:12

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fdbf3a4d-3067-415e-bbd9-476311144736'	System	21 Sep 2020 17:35:12
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 17:35:12

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 15:47'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:34', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'e2dd03fb-4e3a-4fa9-b7b5-25c7421c81f3'	System	21 Sep 2020 22:55:03
User entered 'None (1)'	System	21 Sep 2020 22:55:03

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:38', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'e2dd03fb-4e3a-4fa9-b7b5-25c7421c81f3'	System	21 Sep 2020 22:55:03
User entered 'No (N)'	System	21 Sep 2020 22:55:03

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:41', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'e2dd03fb-4e3a-4fa9-b7b5-25c7421c81f3'	System	21 Sep 2020 22:55:03
User entered 'No (N)'	System	21 Sep 2020 22:55:03

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:52', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'e2dd03fb-4e3a-4fa9-b7b5-25c7421c81f3'	System	21 Sep 2020 22:55:03
User entered 'None (1)'	System	21 Sep 2020 22:55:03

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:54:59', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'e2dd03fb-4e3a-4fa9-b7b5-25c7421c81f3'	System	21 Sep 2020 22:55:03
User entered '21 Sep 2020 18:54'	System	21 Sep 2020 22:55:03

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 16:42'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 2'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '9cf1dc64-166d-43b3-bb0e-8975547985d6'	System	22 Sep 2020 17:27:23
User entered 'None (1)'	System	22 Sep 2020 17:27:23

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:04', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '9cf1dc64-166d-43b3-bb0e-8975547985d6'	System	22 Sep 2020 17:27:23
User entered 'No (N)'	System	22 Sep 2020 17:27:23

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:09', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '9cf1dc64-166d-43b3-bb0e-8975547985d6'	System	22 Sep 2020 17:27:23
User entered 'No (N)'	System	22 Sep 2020 17:27:23

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '9cf1dc64-166d-43b3-bb0e-8975547985d6'	System	22 Sep 2020 17:27:23
User entered 'None (1)'	System	22 Sep 2020 17:27:23

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '9cf1dc64-166d-43b3-bb0e-8975547985d6'	System	22 Sep 2020 17:27:23
User entered '22 Sep 2020 13:27'	System	22 Sep 2020 17:27:23

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 3'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:06', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2e9cea0d-f94e-49a6-92de-fcbf422dd52a'	System	23 Sep 2020 16:24:39
User entered 'None (1)'	System	23 Sep 2020 16:24:39

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2e9cea0d-f94e-49a6-92de-fcbf422dd52a'	System	23 Sep 2020 16:24:39
User entered 'No (N)'	System	23 Sep 2020 16:24:39

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:27', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2e9cea0d-f94e-49a6-92de-fcbf422dd52a'	System	23 Sep 2020 16:24:39
User entered 'No (N)'	System	23 Sep 2020 16:24:39

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:31', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2e9cea0d-f94e-49a6-92de-fcbf422dd52a'	System	23 Sep 2020 16:24:39
User entered 'None (1)'	System	23 Sep 2020 16:24:39

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2e9cea0d-f94e-49a6-92de-fcbf422dd52a' User entered '23 Sep 2020 12:24'	System	23 Sep 2020 16:24:39
	System	23 Sep 2020 16:24:39

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 4'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a571ba9-1e1f-4e7c-bf60-307e350ef19f'	System	24 Sep 2020 16:24:22
User entered 'None (1)'	System	24 Sep 2020 16:24:22

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a571ba9-1e1f-4e7c-bf60-307e350ef19f'	System	24 Sep 2020 16:24:22
User entered 'No (N)'	System	24 Sep 2020 16:24:22

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a571ba9-1e1f-4e7c-bf60-307e350ef19f'	System	24 Sep 2020 16:24:22
User entered 'No (N)'	System	24 Sep 2020 16:24:22

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a571ba9-1e1f-4e7c-bf60-307e350ef19f'	System	24 Sep 2020 16:24:22
User entered 'None (1)'	System	24 Sep 2020 16:24:22

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a571ba9-1e1f-4e7c-bf60-307e350ef19f'	System	24 Sep 2020 16:24:22
User entered '24 Sep 2020 12:24'	System	24 Sep 2020 16:24:22

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 5'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8089639f-e5f1-49a6-b6a0-a4b9764fbc59'	System	25 Sep 2020 16:03:40
User entered 'None (1)'	System	25 Sep 2020 16:03:40

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:01:56', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8089639f-e5f1-49a6-b6a0-a4b9764fbc59'	System	25 Sep 2020 16:03:40
User entered 'No (N)'	System	25 Sep 2020 16:03:40

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8089639f-e5f1-49a6-b6a0-a4b9764fbc59'	System	25 Sep 2020 16:03:40
User entered 'No (N)'	System	25 Sep 2020 16:03:40

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8089639f-e5f1-49a6-b6a0-a4b9764fbc59'	System	25 Sep 2020 16:03:40
User entered 'None (1)'	System	25 Sep 2020 16:03:40

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8089639f-e5f1-49a6-b6a0-a4b9764fbc59'	System	25 Sep 2020 16:03:40
User entered '25 Sep 2020 12:02'	System	25 Sep 2020 16:03:40

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 6'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:49', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71300113-4672-49b6-9d7a-1422c9b70178'	System	26 Sep 2020 18:06:05
User entered 'None (1)'	System	26 Sep 2020 18:06:05

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:52', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71300113-4672-49b6-9d7a-1422c9b70178'	System	26 Sep 2020 18:06:05
User entered 'No (N)'	System	26 Sep 2020 18:06:05

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:54', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71300113-4672-49b6-9d7a-1422c9b70178'	System	26 Sep 2020 18:06:05
User entered 'No (N)'	System	26 Sep 2020 18:06:05

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:05:57', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71300113-4672-49b6-9d7a-1422c9b70178'	System	26 Sep 2020 18:06:05
User entered 'None (1)'	System	26 Sep 2020 18:06:05

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71300113-4672-49b6-9d7a-1422c9b70178'	System	26 Sep 2020 18:06:05
User entered '26 Sep 2020 14:06'	System	26 Sep 2020 18:06:05

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 7'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a0ca6ad-b528-4445-9b8b-474e680ae835'	System	28 Sep 2020 02:19:13
User entered 'None (1)'	System	28 Sep 2020 02:19:13

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:33', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a0ca6ad-b528-4445-9b8b-474e680ae835'	System	28 Sep 2020 02:19:13
User entered 'No (N)'	System	28 Sep 2020 02:19:13

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:18:37', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a0ca6ad-b528-4445-9b8b-474e680ae835'	System	28 Sep 2020 02:19:13
User entered 'No (N)'	System	28 Sep 2020 02:19:13

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:07', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a0ca6ad-b528-4445-9b8b-474e680ae835'	System	28 Sep 2020 02:19:13
User entered 'None (1)'	System	28 Sep 2020 02:19:13

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:10', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a0ca6ad-b528-4445-9b8b-474e680ae835'	System	28 Sep 2020 02:19:13
User entered '27 Sep 2020 22:19'	System	28 Sep 2020 02:19:13

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:28', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:30', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'None (0)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:36', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered 'No (N)'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T13:35:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '527a67b0-6707-4901-9d86-c16cad9ad0d5'	System	21 Sep 2020 17:35:43
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 17:35:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 15:47'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:09', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'None (0)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:28', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered 'No (N)'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-21T18:55:34', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '2d252e33-7868-4435-919e-580e90231039'	System	21 Sep 2020 22:55:37
User entered '21 Sep 2020 18:55'	System	21 Sep 2020 22:55:37

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Sep 2020 16:42'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 2'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:25', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:30', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:32', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:38', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'None (0)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:45', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered 'No (N)'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-22T13:27:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '8b20ed12-1a58-406f-8d10-d70dbc251f01'	System	22 Sep 2020 17:27:51
User entered '22 Sep 2020 13:27'	System	22 Sep 2020 17:27:51

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 3'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:42', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:49', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:52', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:24:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'None (0)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:25:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered 'No (N)'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-23T12:25:17', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c6d761b5-442a-47f3-99ca-978101f0e59e'	System	23 Sep 2020 16:25:19
User entered '23 Sep 2020 12:25'	System	23 Sep 2020 16:25:19

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 4'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:25', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:29', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:31', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:34', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:37', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'None (0)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:45', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered 'No (N)'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-24T12:24:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'f3f6ddb7-a38f-4402-97c6-245499b55b9e'	System	24 Sep 2020 16:24:52
User entered '24 Sep 2020 12:24'	System	24 Sep 2020 16:24:52

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 5'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:32', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:39', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:41', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'None (0)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:49', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered 'No (N)'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-25T12:02:52', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '10d499ce-be19-4644-aa36-1e3895a4b9d4'	System	25 Sep 2020 16:04:17
User entered '25 Sep 2020 12:02'	System	25 Sep 2020 16:04:17

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 6'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:03', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:06', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:09', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:17', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'None (0)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered 'No (N)'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-26T14:06:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ac556ed0-9b92-4d80-aa83-6a20fb5e91f2'	System	26 Sep 2020 18:06:28
User entered '26 Sep 2020 14:06'	System	26 Sep 2020 18:06:28

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	21 Sep 2020 17:07:18
User entered 'Day 7'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:25', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'None (0)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:27', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered 'No (N)'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-09-27T22:19:37', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '1a727ce4-8efe-4b95-bd60-dc59d950d4b7'	System	28 Sep 2020 02:19:43
User entered '27 Sep 2020 22:19'	System	28 Sep 2020 02:19:43

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 17:07:18

US3622211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 17:07:18

US3622211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Oct 2020 18:58:07

US3622211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	08 Oct 2020 18:58:37
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	08 Oct 2020 18:58:37
User entered '28 Sep 2020' reason for change: Data Entry Error	Junlin Long (b) (4)	08 Oct 2020 18:58:37
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	08 Oct 2020 18:58:07
User entered '8 Oct 2020'	System	08 Oct 2020 18:58:07
	Junlin Long (b) (4)	08 Oct 2020 18:58:07
	(b) (4)	

US3622211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	08 Oct 2020 18:58:07

US3622211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered empty.	Junlin Long (b) (4)	08 Oct 2020 18:58:07

US3622211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Oct 2020 18:58:43

US3622211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	08 Oct 2020 18:58:43

US3622211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Oct 2020 18:58:55

US3622211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered '8 Oct 2020'	Junlin Long (b) (4)	08 Oct 2020 18:58:55

US3622211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	08 Oct 2020 18:58:55

US3622211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered empty.	Junlin Long (b) (4)	08 Oct 2020 18:58:55

US3622211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:06:36
User entered 'Yes (Y)'	Junlin Long	08 Oct 2020 18:59:01

US3622211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	08 Oct 2020 18:59:01

US3622211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Oct 2020 17:41:48

US3622211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:56
User entered '13 Oct 2020'	Junlin Long (b) (4)	13 Oct 2020 17:41:48

US3622211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:56
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	13 Oct 2020 17:41:48

US3622211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:56
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Oct 2020 17:41:48

US3622211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:10:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Oct 2020 17:41:54

US3622211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	13 Oct 2020 17:41:54

US3622211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Oct 2020 17:01:27

US3622211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	19 Oct 2020 17:01:27

US3622211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	19 Oct 2020 17:01:27

US3622211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'VISIT2'	System	19 Oct 2020 17:01:27

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '11:37'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '19 Oct 2020 11:37'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '98.1' F	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Oral (Oral)'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '74'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'bpm'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '16'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'breaths/min'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '132'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '88'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '13:25'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '19 Oct 2020 13:25'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '98.2' F	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Oral (Oral)'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '71'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'bpm'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '16'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'breaths/min'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '126'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '87'	Junlin Long (b) (4)	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	20 Oct 2020 12:11:53

US3622211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'No (N)'	Junlin Long (b) (4)	20 Oct 2020 12:12:03

US3622211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	20 Oct 2020 12:12:03

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

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 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'MRNA-1273 OR PLACEBO'	System	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '12:51'	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '19 Oct 2020 12:51'	System	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Right Arm (RIGHT ARM)'	Junlin Long (b) (4)	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'ONCE'	System	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'INTRAMUSCULAR'	System	19 Oct 2020 17:01:55

US3622211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 12:12:21

US3622211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	20 Oct 2020 12:12:21

US3622211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '12:00'	Junlin Long (b) (4)	20 Oct 2020 12:12:21

US3622211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '19 Oct 2020 12:00'	System	20 Oct 2020 12:12:21

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '19 Oct 2020'	Junlin Long (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered '11:53'	(b) (4) Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '19 Oct 2020 11:53'	System	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'No (N)'	Junlin Long (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered empty.	Junlin Long (b) (4)	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered empty.	System	20 Oct 2020 12:12:30

US3622211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Oct 2020 12:12:34

US3622211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	20 Oct 2020 12:12:34

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a79180d4-3679-47bf-8b54-ef86eb5836fa'	System	19 Oct 2020 17:33:38
User entered 'Yes (Y)'	System	19 Oct 2020 17:33:38

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a79180d4-3679-47bf-8b54-ef86eb5836fa' User entered '98.2'	System	19 Oct 2020 17:33:38
	System	19 Oct 2020 17:33:38

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a79180d4-3679-47bf-8b54-ef86eb5836fa'	System	19 Oct 2020 17:33:38
User entered 'No (N)'	System	19 Oct 2020 17:33:38

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:30', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a79180d4-3679-47bf-8b54-ef86eb5836fa'	System	19 Oct 2020 17:33:38
User entered '19 Oct 2020 13:32'	System	19 Oct 2020 17:33:38

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 13:11'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 15:41'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:43:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '12e85677-b9ab-41d7-9ece-0a004c405f83'	System	19 Oct 2020 20:44:18
User entered 'Yes (Y)'	System	19 Oct 2020 20:44:18

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:04', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '12e85677-b9ab-41d7-9ece-0a004c405f83'	System	19 Oct 2020 20:44:18
User entered '97.5'	System	19 Oct 2020 20:44:18

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:09', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '12e85677-b9ab-41d7-9ece-0a004c405f83'	System	19 Oct 2020 20:44:18
User entered 'No (N)'	System	19 Oct 2020 20:44:18

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:13', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '12e85677-b9ab-41d7-9ece-0a004c405f83'	System	19 Oct 2020 20:44:18
User entered '19 Oct 2020 16:44'	System	19 Oct 2020 20:44:18

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 16:36'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 2'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:04:38', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '32b5fd84-5c7e-4924-b52e-51a615ac06f4'	System	20 Oct 2020 18:04:54
User entered 'Yes (Y)'	System	20 Oct 2020 18:04:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:04:46', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '32b5fd84-5c7e-4924-b52e-51a615ac06f4'	System	20 Oct 2020 18:04:54
User entered '98.3'	System	20 Oct 2020 18:04:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:04:49', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '32b5fd84-5c7e-4924-b52e-51a615ac06f4'	System	20 Oct 2020 18:04:54
User entered 'No (N)'	System	20 Oct 2020 18:04:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:04:52', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '32b5fd84-5c7e-4924-b52e-51a615ac06f4'	System	20 Oct 2020 18:04:54
User entered '20 Oct 2020 14:04'	System	20 Oct 2020 18:04:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 3'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:28', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '66822435-7cc0-47b7-b3ee-65d61eaf7f3d'	System	21 Oct 2020 22:55:46
User entered 'Yes (Y)'	System	21 Oct 2020 22:55:46

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '66822435-7cc0-47b7-b3ee-65d61eaf7f3d'	System	21 Oct 2020 22:55:46
User entered '98.5'	System	21 Oct 2020 22:55:46

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:38', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '66822435-7cc0-47b7-b3ee-65d61eaf7f3d'	System	21 Oct 2020 22:55:46
User entered 'No (N)'	System	21 Oct 2020 22:55:46

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:41', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '66822435-7cc0-47b7-b3ee-65d61eaf7f3d'	System	21 Oct 2020 22:55:46
User entered '21 Oct 2020 18:55'	System	21 Oct 2020 22:55:46

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 4'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:27:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '72e9f304-f68c-41f8-b381-5c1592fbc374'	System	22 Oct 2020 22:28:11
User entered 'Yes (Y)'	System	22 Oct 2020 22:28:11

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:02', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '72e9f304-f68c-41f8-b381-5c1592fbc374'	System	22 Oct 2020 22:28:11
User entered '97.8'	System	22 Oct 2020 22:28:11

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '72e9f304-f68c-41f8-b381-5c1592fbc374'	System	22 Oct 2020 22:28:11
User entered 'No (N)'	System	22 Oct 2020 22:28:11

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '72e9f304-f68c-41f8-b381-5c1592fbc374'	System	22 Oct 2020 22:28:11
User entered '22 Oct 2020 18:28'	System	22 Oct 2020 22:28:11

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 5'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:39', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2c06784-1b49-480e-8cb4-99df9caa5040'	System	23 Oct 2020 17:28:55
User entered 'Yes (Y)'	System	23 Oct 2020 17:28:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:44', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2c06784-1b49-480e-8cb4-99df9caa5040' User entered '98.5'	System	23 Oct 2020 17:28:55
	System	23 Oct 2020 17:28:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:47', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2c06784-1b49-480e-8cb4-99df9caa5040'	System	23 Oct 2020 17:28:55
User entered 'No (N)'	System	23 Oct 2020 17:28:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:50', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2c06784-1b49-480e-8cb4-99df9caa5040'	System	23 Oct 2020 17:28:55
User entered '23 Oct 2020 13:28'	System	23 Oct 2020 17:28:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 6'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 7'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:36', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '29e13a86-b06b-4409-a7eb-3fd5aafe6b8d'	System	26 Oct 2020 14:44:54
User entered 'Yes (Y)'	System	26 Oct 2020 14:44:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:43', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '29e13a86-b06b-4409-a7eb-3fd5aafe6b8d'	System	26 Oct 2020 14:44:54
User entered '97.7'	System	26 Oct 2020 14:44:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '29e13a86-b06b-4409-a7eb-3fd5aafe6b8d'	System	26 Oct 2020 14:44:54
User entered 'No (N)'	System	26 Oct 2020 14:44:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:51', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '29e13a86-b06b-4409-a7eb-3fd5aafe6b8d'	System	26 Oct 2020 14:44:54
User entered '26 Oct 2020 10:44'	System	26 Oct 2020 14:44:54

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:35', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86f68775-fede-4ba5-82f3-237b58d9fd95'	System	19 Oct 2020 17:33:48
User entered 'None (1)'	System	19 Oct 2020 17:33:48

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:38', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86f68775-fede-4ba5-82f3-237b58d9fd95'	System	19 Oct 2020 17:33:48
User entered 'No (N)'	System	19 Oct 2020 17:33:48

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86f68775-fede-4ba5-82f3-237b58d9fd95'	System	19 Oct 2020 17:33:48
User entered 'No (N)'	System	19 Oct 2020 17:33:48

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:45', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86f68775-fede-4ba5-82f3-237b58d9fd95'	System	19 Oct 2020 17:33:48
User entered 'None (1)'	System	19 Oct 2020 17:33:48

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:49', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86f68775-fede-4ba5-82f3-237b58d9fd95'	System	19 Oct 2020 17:33:48
User entered '19 Oct 2020 13:32'	System	19 Oct 2020 17:33:48

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 13:11'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 15:41'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3dc15df7-cc3b-4a28-8005-c6fd917cf13e'	System	19 Oct 2020 20:44:50
User entered 'None (1)'	System	19 Oct 2020 20:44:50

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3dc15df7-cc3b-4a28-8005-c6fd917cf13e'	System	19 Oct 2020 20:44:50
User entered 'No (N)'	System	19 Oct 2020 20:44:50

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3dc15df7-cc3b-4a28-8005-c6fd917cf13e'	System	19 Oct 2020 20:44:50
User entered 'No (N)'	System	19 Oct 2020 20:44:50

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:39', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3dc15df7-cc3b-4a28-8005-c6fd917cf13e'	System	19 Oct 2020 20:44:50
User entered 'None (1)'	System	19 Oct 2020 20:44:50

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:44:46', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3dc15df7-cc3b-4a28-8005-c6fd917cf13e'	System	19 Oct 2020 20:44:50
User entered '19 Oct 2020 16:44'	System	19 Oct 2020 20:44:50

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 16:36'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 2'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '28ce1dd1-19e4-43ca-bf28-5c51279bfe91'	System	20 Oct 2020 18:05:14
User entered 'None (1)'	System	20 Oct 2020 18:05:14

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:02', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '28ce1dd1-19e4-43ca-bf28-5c51279bfe91'	System	20 Oct 2020 18:05:14
User entered 'No (N)'	System	20 Oct 2020 18:05:14

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '28ce1dd1-19e4-43ca-bf28-5c51279bfe91'	System	20 Oct 2020 18:05:14
User entered 'No (N)'	System	20 Oct 2020 18:05:14

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '28ce1dd1-19e4-43ca-bf28-5c51279bfe91'	System	20 Oct 2020 18:05:14
User entered 'None (1)'	System	20 Oct 2020 18:05:14

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '28ce1dd1-19e4-43ca-bf28-5c51279bfe91'	System	20 Oct 2020 18:05:14
User entered '20 Oct 2020 14:05'	System	20 Oct 2020 18:05:14

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 3'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:50', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'bc2d5f0b-7b96-4955-8bca-8e7b16f933ff'	System	21 Oct 2020 22:56:05
User entered 'None (1)'	System	21 Oct 2020 22:56:05

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'bc2d5f0b-7b96-4955-8bca-8e7b16f933ff'	System	21 Oct 2020 22:56:05
User entered 'No (N)'	System	21 Oct 2020 22:56:05

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'bc2d5f0b-7b96-4955-8bca-8e7b16f933ff'	System	21 Oct 2020 22:56:05
User entered 'No (N)'	System	21 Oct 2020 22:56:05

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:55:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'bc2d5f0b-7b96-4955-8bca-8e7b16f933ff'	System	21 Oct 2020 22:56:05
User entered 'None (1)'	System	21 Oct 2020 22:56:05

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'bc2d5f0b-7b96-4955-8bca-8e7b16f933ff' User entered '21 Oct 2020 18:56'	System	21 Oct 2020 22:56:05
	System	21 Oct 2020 22:56:05

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 4'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6c36aa61-9683-495f-abc4-f788b7f6df7a'	System	22 Oct 2020 22:28:30
User entered 'None (1)'	System	22 Oct 2020 22:28:30

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6c36aa61-9683-495f-abc4-f788b7f6df7a'	System	22 Oct 2020 22:28:30
User entered 'No (N)'	System	22 Oct 2020 22:28:30

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6c36aa61-9683-495f-abc4-f788b7f6df7a'	System	22 Oct 2020 22:28:30
User entered 'No (N)'	System	22 Oct 2020 22:28:30

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6c36aa61-9683-495f-abc4-f788b7f6df7a'	System	22 Oct 2020 22:28:30
User entered 'None (1)'	System	22 Oct 2020 22:28:30

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '6c36aa61-9683-495f-abc4-f788b7f6df7a' User entered '22 Oct 2020 18:28'	System	22 Oct 2020 22:28:30
	System	22 Oct 2020 22:28:30

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 5'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7897f5b0-a188-4afc-943b-6c9c81d17f77'	System	23 Oct 2020 17:29:08
User entered 'None (1)'	System	23 Oct 2020 17:29:08

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:56', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7897f5b0-a188-4afc-943b-6c9c81d17f77'	System	23 Oct 2020 17:29:08
User entered 'No (N)'	System	23 Oct 2020 17:29:08

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:28:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7897f5b0-a188-4afc-943b-6c9c81d17f77'	System	23 Oct 2020 17:29:08
User entered 'No (N)'	System	23 Oct 2020 17:29:08

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7897f5b0-a188-4afc-943b-6c9c81d17f77'	System	23 Oct 2020 17:29:08
User entered 'None (1)'	System	23 Oct 2020 17:29:08

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7897f5b0-a188-4afc-943b-6c9c81d17f77'	System	23 Oct 2020 17:29:08
User entered '23 Oct 2020 13:29'	System	23 Oct 2020 17:29:08

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 6'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 7'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2d10d49-b5d4-4700-bc38-eb15a00d0c8d'	System	26 Oct 2020 14:45:09
User entered 'None (1)'	System	26 Oct 2020 14:45:09

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:44:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2d10d49-b5d4-4700-bc38-eb15a00d0c8d'	System	26 Oct 2020 14:45:09
User entered 'No (N)'	System	26 Oct 2020 14:45:09

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2d10d49-b5d4-4700-bc38-eb15a00d0c8d'	System	26 Oct 2020 14:45:09
User entered 'No (N)'	System	26 Oct 2020 14:45:09

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:03', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2d10d49-b5d4-4700-bc38-eb15a00d0c8d'	System	26 Oct 2020 14:45:09
User entered 'None (1)'	System	26 Oct 2020 14:45:09

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:07', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd2d10d49-b5d4-4700-bc38-eb15a00d0c8d' User entered '26 Oct 2020 10:45'	System	26 Oct 2020 14:45:09
	System	26 Oct 2020 14:45:09

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:32:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:33:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:33:03', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:33:06', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'None (0)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:33:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851'	System	19 Oct 2020 17:33:58
User entered 'No (N)'	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T13:33:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ead8c679-ee69-4bc7-b389-e7eb65c66851' User entered '19 Oct 2020 13:33'	System	19 Oct 2020 17:33:58
	System	19 Oct 2020 17:33:58

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 13:11'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 15:41'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:10', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:13', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'None (0)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered 'No (N)'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-19T16:45:29', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '4a8e2d6f-5428-489a-a076-27e3073f0cf8'	System	19 Oct 2020 20:45:33
User entered '19 Oct 2020 16:45'	System	19 Oct 2020 20:45:33

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '19 Oct 2020 16:36'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 2'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:17', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'None (0)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:31', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee'	System	20 Oct 2020 18:05:40
User entered 'No (N)'	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-20T14:05:33', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'fea8e19a-7002-4b60-ab5e-8ef5da6fa4ee' User entered '20 Oct 2020 14:05'	System	20 Oct 2020 18:05:40
	System	20 Oct 2020 18:05:40

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 3'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:04', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:06', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:10', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'None (0)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f'	System	21 Oct 2020 22:56:25
User entered 'No (N)'	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-21T18:56:22', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7c61a205-c757-482e-86f1-6de8b4c1d13f' User entered '21 Oct 2020 18:56'	System	21 Oct 2020 22:56:25
	System	21 Oct 2020 22:56:25

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 4'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:34', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:37', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:39', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:41', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:28:58', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:29:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'None (0)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:29:03', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered 'No (N)'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-22T18:29:06', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b4b1f3b-3cc6-4c4a-98a6-4674e6d11885'	System	22 Oct 2020 22:29:10
User entered '22 Oct 2020 18:29'	System	22 Oct 2020 22:29:10

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 5'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:08', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:10', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:12', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'None (0)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered 'No (N)'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-23T13:29:25', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'be5c67f0-6780-4fde-b965-5423c47cb793'	System	23 Oct 2020 17:29:29
User entered '23 Oct 2020 13:29'	System	23 Oct 2020 17:29:29

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 6'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
Data entry locked.	System	19 Oct 2020 17:01:55
User entered 'Day 7'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:14', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:18', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'None (0)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

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 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:26', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered 'No (N)'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-10-26T10:45:29', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ceb01944-89f9-45ac-b146-7a53f8a81256'	System	26 Oct 2020 14:45:37
User entered '26 Oct 2020 10:45'	System	26 Oct 2020 14:45:37

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 17:01:55

US3622211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:09:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:26
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 17:01:55

US3622211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 15:58:48

US3622211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered '26 Oct 2020'	Junlin Long (b) (4)	26 Oct 2020 15:58:48

US3622211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	26 Oct 2020 15:58:48

US3622211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	26 Oct 2020 15:58:48

US3622211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Oct 2020 15:58:51

US3622211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	26 Oct 2020 15:58:51

US3622211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Nov 2020 12:51:12

US3622211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered '2 Nov 2020'	Junlin Long (b) (4)	03 Nov 2020 12:51:12

US3622211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	03 Nov 2020 12:51:12

US3622211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered empty.	Junlin Long (b) (4)	03 Nov 2020 12:51:12

US3622211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:38:56
User entered 'Yes (Y)'	Junlin Long	03 Nov 2020 12:51:14

US3622211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'I'	System	03 Nov 2020 12:51:14

US3622211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:08:21
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Nov 2020 14:00:05

US3622211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:08:21
User entered '10 Nov 2020'	Junlin Long (b) (4)	11 Nov 2020 14:00:05

US3622211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:08:21
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	11 Nov 2020 14:00:05

US3622211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:08:21
User entered empty.	Junlin Long (b) (4)	11 Nov 2020 14:00:05

US3622211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:08:21
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Nov 2020 14:00:09

US3622211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'I'	System	11 Nov 2020 14:00:09

US3622211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:33:24

US3622211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '16 Nov 2020'	Junlin Long (b) (4)	16 Nov 2020 17:33:24

US3622211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	16 Nov 2020 17:33:24

US3622211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'VISIT3'	System	16 Nov 2020 17:33:24

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '16 Nov 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '11:56'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '16 Nov 2020 11:56'	System	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '97.7' F	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Oral (Oral)'	Junlin Long (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '54'	Junlin Long (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'bpm'	System	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '18'	Junlin Long (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'breaths/min'	System	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '138'	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '86'	Junlin Long (b) (4)	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'mmHg'	System	16 Nov 2020 17:34:02

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20

US3622211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20

US3622211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'No (N)'	Junlin Long (b) (4)	16 Nov 2020 17:34:06

US3622211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:34:06

US3622211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Nov 2020 17:34:14

US3622211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '16 Nov 2020'	Junlin Long (b) (4)	16 Nov 2020 17:34:14

US3622211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '12:20'	Junlin Long (b) (4)	16 Nov 2020 17:34:14

**US3622211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '16 Nov 2020 12:20'	System	16 Nov 2020 17:34:14

US3622211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	16 Nov 2020 17:34:18

US3622211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered '1'	System	16 Nov 2020 17:34:18

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[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 (cbf0e702d42c5a3b)', Time: '2020-11-25T19:09:43', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86768a45-7e87-4084-83c7-856e0e6ad1ab'	System	26 Nov 2020 00:09:56
User entered 'No (N)'	System	26 Nov 2020 00:09:56

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-11-25T19:09:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86768a45-7e87-4084-83c7-856e0e6ad1ab'	System	26 Nov 2020 00:09:56
User entered 'No (N)'	System	26 Nov 2020 00:09:56

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-11-25T19:09:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '86768a45-7e87-4084-83c7-856e0e6ad1ab'	System	26 Nov 2020 00:09:56
User entered '25 Nov 2020 19:09:53'	System	26 Nov 2020 00:09:56

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2020-12-03T12:03:16', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd7e4349a-1de7-40e0-ae06-c4f2f0eca338'	System	03 Dec 2020 17:03:29
User entered 'No (N)'	System	03 Dec 2020 17:03:29

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-12-03T12:03:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd7e4349a-1de7-40e0-ae06-c4f2f0eca338'	System	03 Dec 2020 17:03:29
User entered 'No (N)'	System	03 Dec 2020 17:03:29

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-12-03T12:03:23', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'd7e4349a-1de7-40e0-ae06-c4f2f0eca338'	System	03 Dec 2020 17:03:29
User entered '03 Dec 2020 12:03:23'	System	03 Dec 2020 17:03:29

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2020-12-09T00:20:03', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '22b2f786-061b-45a3-a356-78cd63e5f63b'	System	09 Dec 2020 05:20:12
User entered 'No (N)'	System	09 Dec 2020 05:20:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-12-09T00:20:05', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '22b2f786-061b-45a3-a356-78cd63e5f63b'	System	09 Dec 2020 05:20:12
User entered 'No (N)'	System	09 Dec 2020 05:20:12

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-12-09T00:20:09', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '22b2f786-061b-45a3-a356-78cd63e5f63b'	System	09 Dec 2020 05:20:12
User entered '09 Dec 2020 00:20:09'	System	09 Dec 2020 05:20:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[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 (cbf0e702d42c5a3b)', Time: '2020-12-17T17:42:54', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '01b8c8ca-b1d5-4765-9a71-9749f09b7349'	System	17 Dec 2020 22:43:12
User entered 'No (N)'	System	17 Dec 2020 22:43:12

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-12-17T17:43:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '01b8c8ca-b1d5-4765-9a71-9749f09b7349'	System	17 Dec 2020 22:43:12
User entered 'No (N)'	System	17 Dec 2020 22:43:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-12-17T17:43:07', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '01b8c8ca-b1d5-4765-9a71-9749f09b7349'	System	17 Dec 2020 22:43:12
User entered '17 Dec 2020 17:43:07'	System	17 Dec 2020 22:43:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[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 (cbf0e702d42c5a3b)', Time: '2020-12-23T02:37:21', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '763da62b-cf95-43f0-b00f-ed1d4fc53be9'	System	23 Dec 2020 07:37:38
User entered 'No (N)'	System	23 Dec 2020 07:37:38

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-12-23T02:37:29', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '763da62b-cf95-43f0-b00f-ed1d4fc53be9'	System	23 Dec 2020 07:37:38
User entered 'No (N)'	System	23 Dec 2020 07:37:38

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-12-23T02:37:33', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '763da62b-cf95-43f0-b00f-ed1d4fc53be9' User entered '23 Dec 2020 02:37:33'	System	23 Dec 2020 07:37:38
	System	23 Dec 2020 07:37:38

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2020-12-30T18:00:47', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a988e5ab-a45c-4d2a-9679-6be6516bcee0'	System	30 Dec 2020 23:01:09
User entered 'No (N)'	System	30 Dec 2020 23:01:09

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2020-12-30T18:00:55', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a988e5ab-a45c-4d2a-9679-6be6516bcee0'	System	30 Dec 2020 23:01:09
User entered 'No (N)'	System	30 Dec 2020 23:01:09

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2020-12-30T18:01:01', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a988e5ab-a45c-4d2a-9679-6be6516bcee0'	System	30 Dec 2020 23:01:09
User entered '30 Dec 2020 18:01:01'	System	30 Dec 2020 23:01:09

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-01-08T08:53:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered 'Yes (Y)'	System	08 Jan 2021 13:54:12

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-01-08T08:53:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered 'No (N)'	System	08 Jan 2021 13:54:12

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-08T08:53:24', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered 'No (N)'	System	08 Jan 2021 13:54:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-08T08:53:40', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered 'Yes (Y)'	System	08 Jan 2021 13:54:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-08T08:53:51', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 13:54:12

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-08T08:54:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'cc7800b2-bab0-4e43-a5aa-6c09e6834681'	System	08 Jan 2021 13:54:12
User entered '08 Jan 2021 08:54:00'	System	08 Jan 2021 13:54:12

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-01-13T20:30:51', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ef08504f-c2b5-4094-9791-d6c5325a7e6b'	System	14 Jan 2021 01:31:01
User entered 'No (N)'	System	14 Jan 2021 01:31:01

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-01-13T20:30:53', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ef08504f-c2b5-4094-9791-d6c5325a7e6b'	System	14 Jan 2021 01:31:01
User entered 'No (N)'	System	14 Jan 2021 01:31:01

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-13T20:30:58'; User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ef08504f-c2b5-4094-9791-d6c5325a7e6b'	System	14 Jan 2021 01:31:01
User entered '13 Jan 2021 20:30:58'	System	14 Jan 2021 01:31:01

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[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 (cbf0e702d42c5a3b)', Time: '2021-01-21T11:39:46', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c14ee677-86b9-4c8e-9a6a-0c84733cc6f3'	System	21 Jan 2021 16:40:06
User entered 'No (N)'	System	21 Jan 2021 16:40:06

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-01-21T11:39:48', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c14ee677-86b9-4c8e-9a6a-0c84733cc6f3'	System	21 Jan 2021 16:40:06
User entered 'No (N)'	System	21 Jan 2021 16:40:06

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-01-21T11:39:59', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'c14ee677-86b9-4c8e-9a6a-0c84733cc6f3'	System	21 Jan 2021 16:40:06
User entered '21 Jan 2021 11:39:59'	System	21 Jan 2021 16:40:06

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-02-04T03:15:11', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7253a16a-2b1f-4895-bba1-ac09546110e4'	System	04 Feb 2021 08:15:22
User entered 'No (N)'	System	04 Feb 2021 08:15:22

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-02-04T03:15:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7253a16a-2b1f-4895-bba1-ac09546110e4'	System	04 Feb 2021 08:15:22
User entered 'No (N)'	System	04 Feb 2021 08:15:22

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-02-04T03:15:20', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7253a16a-2b1f-4895-bba1-ac09546110e4'	System	04 Feb 2021 08:15:22
User entered '04 Feb 2021 03:15:20'	System	04 Feb 2021 08:15:22

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-02-11T08:28:28'; User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'abcdaa33-2e05-4692-b6ec-4b97ce0a2c42'	System	11 Feb 2021 13:28:36
User entered 'No (N)'	System	11 Feb 2021 13:28:36

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-02-11T08:28:30', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'abcdaa33-2e05-4692-b6ec-4b97ce0a2c42'	System	11 Feb 2021 13:28:36
User entered 'No (N)'	System	11 Feb 2021 13:28:36

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-02-11T08:28:34', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'abcdaa33-2e05-4692-b6ec-4b97ce0a2c42'	System	11 Feb 2021 13:28:36
User entered '11 Feb 2021 08:28:34'	System	11 Feb 2021 13:28:36

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-02-17T10:50:15', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3038660c-d9d3-4609-a42f-ec82f1d2721a'	System	17 Feb 2021 15:50:29
User entered 'No (N)'	System	17 Feb 2021 15:50:29

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-02-17T10:50:19', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3038660c-d9d3-4609-a42f-ec82f1d2721a'	System	17 Feb 2021 15:50:29
User entered 'No (N)'	System	17 Feb 2021 15:50:29

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-02-17T10:50:25', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '3038660c-d9d3-4609-a42f-ec82f1d2721a'	System	17 Feb 2021 15:50:29
User entered '17 Feb 2021 10:50:25'	System	17 Feb 2021 15:50:29

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-02-26T20:31:41-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '92046d60-9777-493d-a32a-4c55c6b29c67'	System	27 Feb 2021 01:31:53
User entered 'No (N)'	System	27 Feb 2021 01:31:53

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-02-26T20:31:43-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '92046d60-9777-493d-a32a-4c55c6b29c67'	System	27 Feb 2021 01:31:53
User entered 'No (N)'	System	27 Feb 2021 01:31:53

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-02-26T20:31:46-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '92046d60-9777-493d-a32a-4c55c6b29c67'	System	27 Feb 2021 01:31:53
User entered '26 Feb 2021 20:31:46'	System	27 Feb 2021 01:31:53

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-03-03T22:42:13-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '539b061f-7232-45ca-8ded-06ea388dd173'	System	04 Mar 2021 03:42:22
User entered 'No (N)'	System	04 Mar 2021 03:42:22

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-03-03T22:42:15-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '539b061f-7232-45ca-8ded-06ea388dd173'	System	04 Mar 2021 03:42:22
User entered 'No (N)'	System	04 Mar 2021 03:42:22

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-03T22:42:19-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '539b061f-7232-45ca-8ded-06ea388dd173'	System	04 Mar 2021 03:42:22
User entered '03 Mar 2021 22:42:19'	System	04 Mar 2021 03:42:22

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-03-10T00:37:53-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ad8e9b8a-c77b-40ff-ac1b-9295a471f3a5'	System	10 Mar 2021 05:38:11
User entered 'No (N)'	System	10 Mar 2021 05:38:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-03-10T00:37:58-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ad8e9b8a-c77b-40ff-ac1b-9295a471f3a5'	System	10 Mar 2021 05:38:11
User entered 'No (N)'	System	10 Mar 2021 05:38:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-10T00:38:04-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'ad8e9b8a-c77b-40ff-ac1b-9295a471f3a5' User entered '10 Mar 2021 00:38:04'	System	10 Mar 2021 05:38:11
	System	10 Mar 2021 05:38:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-03-18T06:24:47-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7cce540f-4c89-47c5-8879-293591e1aad7'	System	18 Mar 2021 10:24:59
User entered 'No (N)'	System	18 Mar 2021 10:24:59

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-03-18T06:24:50-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7cce540f-4c89-47c5-8879-293591e1aad7'	System	18 Mar 2021 10:24:59
User entered 'No (N)'	System	18 Mar 2021 10:24:59

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-18T06:24:55-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7cce540f-4c89-47c5-8879-293591e1aad7'	System	18 Mar 2021 10:24:59
User entered '18 Mar 2021 06:24:55'	System	18 Mar 2021 10:24:59

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-03-24T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b686e14-806e-4b36-967a-2ee55eb31009'	System	24 Mar 2021 04:03:42
User entered 'No (N)'	System	24 Mar 2021 04:03:42

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-03-24T00:02:36-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b686e14-806e-4b36-967a-2ee55eb31009'	System	24 Mar 2021 04:03:42
User entered 'No (N)'	System	24 Mar 2021 04:03:42

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-24T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '0b686e14-806e-4b36-967a-2ee55eb31009' User entered '24 Mar 2021 00:02:39'	System	24 Mar 2021 04:03:42
	System	24 Mar 2021 04:03:42

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-03-31T01:39:24-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '5526a2ab-437c-4596-b64c-a50804dfd62e'	System	31 Mar 2021 05:39:39
User entered 'No (N)'	System	31 Mar 2021 05:39:39

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-03-31T01:39:32-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '5526a2ab-437c-4596-b64c-a50804dfd62e'	System	31 Mar 2021 05:39:39
User entered 'No (N)'	System	31 Mar 2021 05:39:39

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-31T01:39:35-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '5526a2ab-437c-4596-b64c-a50804dfd62e' User entered '31 Mar 2021 01:39:35'	System	31 Mar 2021 05:39:39
	System	31 Mar 2021 05:39:39

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 (cbf0e702d42c5a3b)', Time: '2021-04-07T00:15:56-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7be7957e-4d9b-441b-b056-be7852846080'	System	07 Apr 2021 04:16:07
User entered 'No (N)'	System	07 Apr 2021 04:16:07

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-04-07T00:15:59-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7be7957e-4d9b-441b-b056-be7852846080'	System	07 Apr 2021 04:16:07
User entered 'No (N)'	System	07 Apr 2021 04:16:07

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-04-07T00:16:04-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7be7957e-4d9b-441b-b056-be7852846080'	System	07 Apr 2021 04:16:07
User entered '07 Apr 2021 00:16:04'	System	07 Apr 2021 04:16:07

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

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 (cbf0e702d42c5a3b)', Time: '2021-04-14T00:29:29-06:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '97822932-03dc-4c64-abc8-deb66e1da217'	System	14 Apr 2021 06:29:36
User entered 'No (N)'	System	14 Apr 2021 06:29:36

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-04-14T00:29:22-06:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '97822932-03dc-4c64-abc8-deb66e1da217'	System	14 Apr 2021 06:29:36
User entered 'No (N)'	System	14 Apr 2021 06:29:36

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-04-14T00:29:33-06:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '97822932-03dc-4c64-abc8-deb66e1da217'	System	14 Apr 2021 06:29:36
User entered '14 Apr 2021 00:29:33'	System	14 Apr 2021 06:29:36

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-04-21T12:47:17-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71e1a379-4a08-401f-8df9-121373aaa5a4'	System	21 Apr 2021 16:47:32
User entered 'No (N)'	System	21 Apr 2021 16:47:32

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-04-21T12:47:24-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71e1a379-4a08-401f-8df9-121373aaa5a4'	System	21 Apr 2021 16:47:32
User entered 'No (N)'	System	21 Apr 2021 16:47:32

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-04-21T12:47:27-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '71e1a379-4a08-401f-8df9-121373aaa5a4'	System	21 Apr 2021 16:47:32
User entered '21 Apr 2021 12:47:27'	System	21 Apr 2021 16:47:32

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:57:11

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

[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 (cbf0e702d42c5a3b)', Time: '2021-04-29T22:25:45-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7e53877c-b1e4-498b-a9f0-218deff4c15a'	System	30 Apr 2021 02:26:09
User entered 'No (N)'	System	30 Apr 2021 02:26:09

US3622211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:09:10

Have you been exposed to someone with 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 (cbf0e702d42c5a3b)', Time: '2021-04-29T22:26:02-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7e53877c-b1e4-498b-a9f0-218deff4c15a'	System	30 Apr 2021 02:26:09
User entered 'No (N)'	System	30 Apr 2021 02:26:09

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-04-29T22:26:06-04:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: '7e53877c-b1e4-498b-a9f0-218deff4c15a'	System	30 Apr 2021 02:26:09
User entered '29 Apr 2021 22:26:06'	System	30 Apr 2021 02:26:09

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:57:11

**US3622211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:09:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:57:11
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:57:11

US3622211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:10

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 19:26:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-02T22:28:11-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a72d2779-9f3a-43cc-b1ad-4e5134f9902d'	System	03 Mar 2021 03:28:20
User entered 'No (N)'	System	03 Mar 2021 03:28:20

US3622211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:09:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:26:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (cbf0e702d42c5a3b)', Time: '2021-03-02T22:28:16-05:00', User OID: 'PatientReportedOutcome (US3622211)', ODM File OID: 'a72d2779-9f3a-43cc-b1ad-4e5134f9902d'	System	03 Mar 2021 03:28:20
User entered '02 Mar 2021 22:28:16'	System	03 Mar 2021 03:28:20

US3622211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	14 Dec 2020 15:29:37

US3622211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '14 Dec 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	14 Dec 2020 15:29:37

US3622211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	14 Dec 2020 15:29:37

US3622211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	14 Dec 2020 15:29:37

US3622211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	14 Dec 2020 15:29:44

US3622211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:09:20
User entered 'I'	System	14 Dec 2020 15:29:44

US3622211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Jan 2021 14:30:14

US3622211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '20 Jan 2021'	Junlin Long (b) (4)	20 Jan 2021 14:30:14

US3622211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	20 Jan 2021 14:30:14

US3622211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	20 Jan 2021 14:30:14

US3622211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	Junlin Long (b) (4)	20 Jan 2021 14:30:18

US3622211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User entered '1'	System	20 Jan 2021 14:30:18

US3622211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:42:07

US3622211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:42:07

US3622211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:42:07

US3622211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:42:07

US3622211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:42:15

US3622211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User entered '1'	System	18 Feb 2021 13:42:15

US3622211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:08:50

US3622211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:08:50

US3622211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:08:50

US3622211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:08:50

US3622211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:09:04

US3622211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:37:19
User entered 'I'	System	16 Mar 2021 15:09:04

US3622211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Apr 2021 17:08:30
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '19 Apr 2021'	Junlin Long (b) (4)	19 Apr 2021 17:08:30
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	19 Apr 2021 17:08:30
	(b) (4)	

**US3622211**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:09:10**

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 17:08:30

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '19 Apr 2021'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '12:46'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

---

Audit	User	Time (GMT)
User entered '19 Apr 2021 12:46'	System	19 Apr 2021 17:08:48

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '98.5' F	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Oral (Oral)'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '92'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

**US3622211**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:09:10**

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 17:08:48

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '20'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 17:08:48

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '134'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 17:08:48

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '85'	Junlin Long (b) (4)	19 Apr 2021 17:08:48
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 17:08:48

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	19 Apr 2021 17:08:52
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	19 Apr 2021 17:08:52
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Apr 2021 17:09:00
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '19 Apr 2021'	Junlin Long (b) (4)	19 Apr 2021 17:09:00
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered '13:00'	Junlin Long (b) (4)	19 Apr 2021 17:09:00
	(b) (4)	

**US3622211**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:09:10**

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

---

Audit	User	Time (GMT)
User entered '19 Apr 2021 13:00'	System	19 Apr 2021 17:09:00

---

US3622211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:41:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Apr 2021 17:09:03
	(b) (4)	

US3622211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 17:09:03

---

US3622211

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:32

US3622211

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:32

US3622211

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Clinic (Clinic)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:32

US3622211

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

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:58:32

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:48
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:47:49

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:48
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 19:47:49

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Placebo (Placebo)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:23:35
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	19 Jan 2021 16:58:43
	(b) (4)	

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 15:23:35
User entered 'Placebo (Placebo)'	Junlin Long (b) (4)	19 Jan 2021 16:58:43
	(b) (4)	

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '1'	System	19 Jan 2021 16:58:43

US3622211

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

Form: Unblinding

Generated On: 10 Jun 2021 09:09:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '1'	System	19 Jan 2021 16:58:43

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '72' in	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '240' lb	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '32.61791'	System	19 Jan 2021 17:58:52
DataPoint set to visible.	System	19 Jan 2021 16:58:43

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '72' in	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '240' lb	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '32.61791'	System	19 Jan 2021 17:58:52
DataPoint set to visible.	System	19 Jan 2021 16:58:43

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '10:45' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19 Jan 2021 10:45'	System	19 Jan 2021 17:59:28
User entered empty.	System	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '98.4' F reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '80' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'bpm'	System	19 Jan 2021 17:59:28
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '16' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'breaths/min'	System	19 Jan 2021 17:59:28
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '137' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	19 Jan 2021 17:59:28
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 17:59:28
User entered '91' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 17:59:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	19 Jan 2021 17:59:28
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '72' in	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '240' lb	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:09:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '32.61791'	System	19 Jan 2021 17:58:52
DataPoint set to visible.	System	19 Jan 2021 16:58:43

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '12:14' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19 Jan 2021 12:14'	System	19 Jan 2021 18:00:06
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '98.2' F reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 17:58:52

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '78' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'bpm'	System	19 Jan 2021 18:00:06
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '18' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'breaths/min'	System	19 Jan 2021 18:00:06
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '133' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	19 Jan 2021 18:00:06
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 18:00:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Jan 2021 18:00:06
User entered '92' reason for change: Data Entry Error	Junlin Long (b) (4)	19 Jan 2021 18:00:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Jan 2021 17:58:52
User entered empty.	Junlin Long (b) (4)	19 Jan 2021 17:58:52
	(b) (4)	

US3622211

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	19 Jan 2021 18:00:06
User entered empty.	System	19 Jan 2021 17:58:52

US3622211

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:19

US3622211

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:19

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mRNA-1273'	System	19 Jan 2021 16:58:54
DataPoint set to visible.	System	19 Jan 2021 16:58:43

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '11:43'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19 Jan 2021 11:43'	System	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'ONCE'	System	19 Jan 2021 16:58:54

US3622211

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

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 16:58:54

US3622211

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:32

US3622211

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:32

US3622211

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '10:54'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:32

US3622211

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19 Jan 2021 10:54'	System	19 Jan 2021 18:00:32

US3622211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:41

US3622211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '19 Jan 2021'	Junlin Long (b) (4)	19 Jan 2021 18:00:41

US3622211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '10:57'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:41

US3622211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:09:10

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '19 Jan 2021 10:57'	System	19 Jan 2021 18:00:41

US3622211

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

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Jan 2021 18:00:44

US3622211

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

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '1'	System	19 Jan 2021 18:00:44

US3622211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'No (N)'	Junlin Long (b) (4)	15 Feb 2021 18:15:28

US3622211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	Junlin Long (b) (4)	15 Feb 2021 18:15:28

US3622211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	Junlin Long (b) (4)	15 Feb 2021 18:15:28

US3622211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	Junlin Long (b) (4)	15 Feb 2021 18:15:28

US3622211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:32:44

US3622211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User entered '1'	System	15 Feb 2021 17:32:44

US3622211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:17:16
User entered '1'	System	15 Feb 2021 17:32:44
DataPoint set to visible.	System	15 Feb 2021 17:32:44

US3622211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:15

US3622211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:15

US3622211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:15

US3622211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'OLD29'	System	15 Feb 2021 17:33:15

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '15 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '11:44'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '15 Feb 2021 11:44'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '98.4' F	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '90'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'bpm'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'breaths/min'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '131'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '81'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '15 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '12:58'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '15 Feb 2021 12:58'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '98.3' F	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '88'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'bpm'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '20'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'breaths/min'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '114'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '83'	Junlin Long (b) (4)	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mmHg'	System	15 Feb 2021 18:16:20

US3622211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:30

US3622211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Feb 2021 18:16:30

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'mRNA-1273'	System	15 Feb 2021 17:33:55
DataPoint set to visible.	System	15 Feb 2021 17:32:44

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered '12:26'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '15 Feb 2021 12:26'	System	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'ONCE'	System	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:09:10

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 17:33:55

US3622211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:16:33
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Feb 2021 18:16:37

US3622211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:28
User entered '1'	System	15 Feb 2021 18:16:37

US3622211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Feb 2021 14:31:27

US3622211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered '22 Feb 2021'	Junlin Long (b) (4)	22 Feb 2021 14:31:27

US3622211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	22 Feb 2021 14:31:27

US3622211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:09:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	22 Feb 2021 14:31:27

US3622211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Feb 2021 14:31:31

US3622211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:09:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:46
User entered '1'	System	22 Feb 2021 14:31:31

US3622211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:22

US3622211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '15 Mar 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:22

US3622211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[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 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	15 Mar 2021 16:23:22

US3622211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:09:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered 'OLD57'	System	15 Mar 2021 16:23:22

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '15 Mar 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '11:48'	Junlin Long (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered '15 Mar 2021 11:48'	System	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '98.6' F	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '94'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered 'bpm'	System	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '16'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered 'breaths/min'	System	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '128'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered 'mmHg'	System	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '92'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered 'mmHg'	System	15 Mar 2021 16:23:41

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21

US3622211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:09:10

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21

US3622211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:46

US3622211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:09:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Mar 2021 16:23:46

US3622211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Mar 2021 16:23:58

US3622211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '15 Mar 2021'	Junlin Long (b) (4)	15 Mar 2021 16:23:58

US3622211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:06:40
User entered '11:55'	Junlin Long (b) (4)	15 Mar 2021 16:23:58

US3622211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:09:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:21
User entered '15 Mar 2021 11:55'	System	15 Mar 2021 16:23:58

US3622211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:09:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:17
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:26:51
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	14 Dec 2020 14:27:21

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	08 Jan 2021 19:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 19:28:42
Data point term sent to Coder	System	08 Jan 2021 19:28:13
User entered 'hypercholesterolemia'	Junlin Long (b) (4)	08 Jan 2021 19:27:49
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:56
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:13:40
User entered '1 Jan 2021' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:13:40
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
User entered empty.	System	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User entered '11 Jan 2021' reason for change: New Information	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
User entered empty.	System	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:14:30
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

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 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
User entered '0'	System	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03
User entered '1'	System	08 Jan 2021 19:38:56
User entered '0'	System	08 Jan 2021 19:27:49

US3622211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:03

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:04:11
User entered 'USA-US085-2021-mRNA-1273-P301000001'	System	11 Jan 2021 17:04:04
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 17:04:04

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Nervous system disorders, HLG: Encephalopathies, HLT: Encephalopathies NEC, PT: Encephalopathy, LLT: Encephalopathy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Jan 2021 16:02:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Jan 2021 16:02:49
Data point term sent to Coder	System	25 Jan 2021 16:02:03
Coding entries removed.	Junlin Long (b) (4)	25 Jan 2021 16:02:01
User entered 'encephalopathy' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:02:01
User coded data point as SOC: Psychiatric disorders, HLG: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 19:35:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Jan 2021 19:35:43
Data point term sent to Coder	System	08 Jan 2021 19:35:17
User entered 'altered mental status'	Junlin Long (b) (4)	08 Jan 2021 19:35:08
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:10**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 19:35:08

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US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Jan 2021 19:35:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Jan 2021 19:35:08
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	08 Jan 2021 19:35:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	08 Jan 2021 19:35:32
User entered '2 Jan 2021' reason for change: Data Entry Error	Junlin Long (b) (4)	08 Jan 2021 19:35:32
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	08 Jan 2021 19:35:08
User entered empty.	System	08 Jan 2021 19:35:08
	Junlin Long (b) (4)	08 Jan 2021 19:35:08
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 19:35:08

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US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 4 (Grade 4)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:31:14
User entered '1' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	02 Mar 2021 18:31:14
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:05:37
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'according to medical records, participant was not given any medications for this sae.' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:31:49
Signature has been broken.	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:31:14
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	02 Mar 2021 18:31:14
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:44:32
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:07:46

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 15:56:33
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:09:59
User entered '1' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:09:45
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 14:26:33
User entered '0'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 14:54:17
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User closed query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 18:55:34
Query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'emails with medical records were resent again today.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	25 Feb 2021 18:06:41
User opened query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 01:48:43
User closed query 'PV Query: Please have all events and possible diagnostics reported and not limited to a single sign.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 18:26:25
User closed query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 18:26:22
Query 'PV Query: Please have all events and possible diagnostics reported and not limited to a single sign.' answered with 'based on medical records, events and possible diagnostics have been reported.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 20:05:32

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'the medical records were sent to the email Safety_Moderna@iqvia.com on February 8th, 2021 and have been resent today (February 23rd, 2021).' (Site from Safety).	Junlin Long (b) (4) (b) (4)	23 Feb 2021 20:02:45
User opened query 'PV Query: Please have all events and possible diagnostics reported and not limited to a single sign.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 18:50:50
User opened query 'PV Query: Email was not received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 18:50:42
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User closed query 'PV Query: Please confirm if any additional treatment was given for the event. If so, please add medications to the concomitant medication eCRF page.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:33:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Case clarification required:' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:33:53

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Case clarification required:' answered with 'medical records have been sent to Safety_Moderna@iqvia.com.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 18:35:06
Query 'PV Query: Please confirm if any additional treatment was given for the event. If so, please add medications to the concomitant medication eCRF page.' answered with 'medications updated on conmed page' (Site from Safety).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 18:27:32

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT CALLED TO REPORT THAT ON 1/1/2021, THEY DEVELOPED ALTERED MENTAL STATUS AND WERE ADMITTED AT BAPTIST WEST KENDALL FOR A 24-HOUR OBSERVATION. ALL TESTING WAS NEGATIVE AND PATIENT REPORTS SYMPTOMS RESOLVED AND THEY WERE DISCHARGED ON 1/2/2021 AT 5:00 P.M. THEY WERE STARTED ON ASPIRIN 81 MG AND ATORVASTATIN 20 MG DAILY.  update: The participant went to the ER on 01/01/2021 for confusion. Per hospital medical records his confusion lasted about 1 hour. He was discharged on 01/02/2021. Per hospital records brain MRI on 01/02/2021 revealed a 2cm arachnoid cyst and right mastoiditis. Chest x-ray on 01/01/2021 revealed peripheral interstitial infiltrates. Head MRA, chest CT, and CT brain were all negative. EKG on 01/01/2021 revealed sinus tachycardia. Echocardiogram on 01/02/2021 revealed grade 1 diastolic dysfunction. Carotid duplex on 01/02/2021 was normal. The patient's confusion fully recovered, and he was discharged on 01/02/2021. Discharge diagnoses were encephalopathy, brain TIA presumed, transient global amnesia presumed, arachnoid cyst, right side mastoiditis, hypertension, grade 1 diastolic dysfunction, peripheral infiltrates, and sinus tachycardia.' reason for change: New Information	Junlin Long (b) (4) (b) (4)	29 Jan 2021 17:02:49
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)	26 Jan 2021 15:56:31
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 'tested twice on 1/1/2021, both covid-19 test results: negative' (Site from Safety).	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:11:50

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if any additional treatment was given for the event. If so, please add medications to the concomitant medication eCRF page.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 14:26:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 14:26:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. Case clarification required:' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 14:26:40
User entered 'participant called to report that on 1/1/2021, they developed altered mental status and were admitted at Baptist West Kendall for a 24-hour observation. all testing was negative and patient reports symptoms resolved and they were discharged on 1/2/2021 at 5:00 p.m. they were started on aspirin 81 mg and atorvastatin 20 mg daily.'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:35:08

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 19:35:08

---

US3622211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 19:35:08

---

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:09:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 19:35:08

---

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Jan 2021 18:49:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:49:56
Data point term sent to Coder	System	25 Jan 2021 14:41:35
User entered 'brain tia presumed'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
User entered empty.	System	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
User entered empty.	System	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Junlin Long (b) (4)	25 Jan 2021 16:03:01
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4)	25 Jan 2021 14:41:05
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:07:46
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Jan 2021 16:03:01
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	25 Jan 2021 16:03:01
User entered '1'	(b) (4)	
	Junlin Long (b) (4)	25 Jan 2021 14:41:05
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:01
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4)	25 Jan 2021 14:41:05
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:01
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:01
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

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 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:01
User entered 'participant was diagnosed with this during hospitalization.'	(b) (4) Junlin Long (b) (4)	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
User entered '0'	System	25 Jan 2021 16:03:01
User entered '1'	System	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
User entered '1'	System	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:57
User entered '0'	System	25 Jan 2021 14:41:05

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Nervous system disorders, HLG: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Transient global amnesia, LLT: Transient global amnesia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Jan 2021 21:12:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Jan 2021 21:12:53
Data point term sent to Coder	System	25 Jan 2021 14:43:36
User entered 'tga presumed (Transient global amnesia)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
User entered empty.	System	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
User entered empty.	System	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Junlin Long (b) (4)	25 Jan 2021 16:03:58
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4)	25 Jan 2021 14:42:55
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	25 Jan 2021 16:03:58
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	25 Jan 2021 14:42:55
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	25 Jan 2021 16:03:58
User entered '1'	(b) (4)	
	Junlin Long (b) (4)	25 Jan 2021 14:42:55
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:58
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:58
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:58
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

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 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty; reason for change New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 16:03:58
User entered 'participant was diagnosed with this during hospitalization.'	(b) (4) Junlin Long (b) (4)	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
User entered '0'	System	25 Jan 2021 16:03:58
User entered '1'	System	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
User entered '1'	System	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:55
User entered '0'	System	25 Jan 2021 14:42:55

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:48
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)	11 Mar 2021 08:08:44
User coded data point as SOC: Nervous system disorders, HLGT: Nervous system neoplasms benign, HLT: Nervous system cysts and polyps, PT: Arachnoid cyst, LLT: Arachnoid cyst - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:12:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:12:56
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 'ae updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	10 Mar 2021 17:10:08
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4) (b) (4)	10 Mar 2021 17:10:01 10 Mar 2021 17:09:53
Signature has been broken.	Junlin Long (b) (4) (b) (4)	10 Mar 2021 17:09:53
User entered 'benign ARACHNOID CYST' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	10 Mar 2021 17:09:53
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)	08 Mar 2021 07:00:58
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:07:46

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Nervous system neoplasms benign, HLT: Nervous system cysts and polyps, PT: Arachnoid cyst, LLT: Arachnoid cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 14:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 14:46:52
Data point term sent to Coder	System	25 Jan 2021 14:45:36
User entered 'arachnoid cyst'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:09:10**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:45:05

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US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:45:05

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US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User closed query 'Per CDM: During OL-D1 visit, as per CCG V4.0 page 47, if adverse event started BEFORE first dose then Action taken with investigational product should be 'Not applicable'. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 08:19:40
Query 'Per CDM: During OL-D1 visit, as per CCG V4.0 page 47, if adverse event started BEFORE first dose then Action taken with investigational product should be 'Not applicable'. Kindly review and update appropriately. Thank you' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 18:32:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	08 Feb 2021 18:32:07
User opened query 'Per CDM: During OL-D1 visit, as per CCG V4.0 page 47, if adverse event started BEFORE first dose then Action taken with investigational product should be 'Not applicable'. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:31:51
User entered 'None (NONE)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:05

US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:45:05

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US3622211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:45:05

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US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Mastoiditis, LLT: Mastoiditis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Jan 2021 16:24:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 16:24:19
Data point term sent to Coder	System	25 Jan 2021 14:46:37
User entered 'right side mastoiditis'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:45:47

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US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

US3622211

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:45:47

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:09:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:45:47

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**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:09:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:45:47

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US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 14:49:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 14:49:49
Data point term sent to Coder	System	25 Jan 2021 14:49:38
User entered 'hypertension'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:48:51

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US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:48:51

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US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:48:51

US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:48:51

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US3622211

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:48:51

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US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Diastolic dysfunction, LLT: Diastolic dysfunction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 14:50:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 14:50:57
Data point term sent to Coder	System	25 Jan 2021 14:50:39
User entered 'grade 1 diastolic dysfunction'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:49:58

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:49:58

---

US3622211

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:49:58

---

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Lung infiltration, LLT: Lung infiltration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:01:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:01:48
Data point term sent to Coder	System	30 Mar 2021 15:06:30
User closed query 'For coding purposes, please clarify, PERIPHERAL INTERSTITIAL INFILTRATES. Is this Lymphocytic infiltration, Tissue infiltration, Interstitial fluid increased, edema or something else. Please update the term with your response' (Site from System).	System	30 Mar 2021 15:05:53
Query 'For coding purposes, please clarify, PERIPHERAL INTERSTITIAL INFILTRATES. Is this Lymphocytic infiltration, Tissue infiltration, Interstitial fluid increased, edema or something else. Please update the term with your response' answered with 'correct as entered; entered as what medical records state; no additional information provided in medical records' (Site from System).	Junlin Long (b) (4) (b) (4)	30 Mar 2021 15:05:53
User opened query 'For coding purposes, please clarify, PERIPHERAL INTERSTITIAL INFILTRATES. Is this Lymphocytic infiltration, Tissue infiltration, Interstitial fluid increased, edema or something else. Please update the term with your response' (Site from System).	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:38:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Mar 2021 14:06:40
Data point term sent to Coder	System	19 Mar 2021 13:41:59
User closed query 'DM-Coding: AE term - PERIPHERAL INFILTRATES, Please enter the body site/location for the event INFILTRATES. Please update the reported term.' (Site from System).	System	19 Mar 2021 13:41:55

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
Query 'DM-Coding: AE term - PERIPHERAL INFILTRATES, Please enter the body site/location for the event INFILTRATES. Please update the reported term.' answered with 'updated' (Site from System).	Junlin Long (b) (4)	19 Mar 2021 13:41:55
Data point term sent to Coder Signature has been broken.	System Junlin Long (b) (4)	19 Mar 2021 13:40:58 19 Mar 2021 13:40:46
User entered 'PERIPHERAL interstitial INFILTRATES' reason for change: Per Query Resolution	Junlin Long (b) (4)	19 Mar 2021 13:40:46
User opened query 'DM-Coding: AE term - PERIPHERAL INFILTRATES, Please enter the body site/location for the event INFILTRATES. Please update the reported term.' (Site from System). User signature succeeded.	Coder Import (b) (4) Susanne Doblecki-Lewis (b) (4)	19 Mar 2021 09:33:29 12 Feb 2021 14:07:46
Data point term sent to Coder User entered 'peripheral infiltrates'	System Junlin Long (b) (4)	25 Jan 2021 14:52:41 25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:51:43

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US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:51:43

US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:51:43

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US3622211

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:51:43

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US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Jan 2021 14:52:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:52:49
Data point term sent to Coder	System	25 Jan 2021 14:52:40
User entered 'sinus tachycardia'	Junlin Long (b) (4)	25 Jan 2021 14:52:33
	(b) (4)	

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:09:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:09:10**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 14:52:33

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US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '0'	Junlin Long (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:19
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:52:33

**US3622211**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 10 Jun 2021 09:09:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 14:52:33

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US3622211

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:09:10

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 14:52:33

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:09:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:06:55
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:30:40

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 05:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:53:49
Data point term sent to Coder	System	21 Sep 2020 19:32:20
User entered 'proscar'	(b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 08:13:29
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'data entry error' (Site from DM).	Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:32:47
Signature has been broken.	Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:32:15
User entered 'No (N)' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	16 Nov 2020 17:32:15
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an MH recorded (MH#1) that matches this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:22:34
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'enlarge prostate'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:20:02
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
Signature has been broken.	(b) (4) Junlin Long (b) (4)	20 Oct 2020 12:10:56
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '5'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'un Apr 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
Signature has been broken.	(b) (4) Junlin Long (b) (4)	23 Oct 2020 14:28:55
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	23 Oct 2020 14:28:55
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:06:14
Signature has been broken.	(b) (4) Junlin Long (b) (4)	23 Oct 2020 14:28:55
User entered '9 Oct 2020' reason for change: New Information	(b) (4) Junlin Long (b) (4)	23 Oct 2020 14:28:55
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:14:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:31:36

US3622211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:10**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 19:31:36

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US3622211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:10**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 19:31:36

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US3622211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:09:10**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 19:31:36

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US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:04
Data point term sent to Coder	System	03 Mar 2021 14:22:27
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Data point term sent to Coder	System	03 Mar 2021 14:20:26
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:00:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:00:47
Data point term sent to Coder	System	08 Jan 2021 19:38:20
User entered 'aspirin'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Junlin Long (b) (4)	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	(b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Junlin Long (b) (4)	14 Jan 2021 15:09:15
User entered 'prevention of blood clot'	(b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Junlin Long (b) (4)	14 Jan 2021 15:09:15
User entered '81'	(b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered 'mg (mg)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered 'once daily (QD)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered 'Oral (ORAL)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered empty.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:12:45
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:01:04
User entered '1 Jan 2021' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:01:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered '2 Jan 2021'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Junlin Long (b) (4)	14 Jan 2021 15:09:15
User entered '0'	(b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:12:45
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:01:04
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:01:04
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4) Junlin Long (b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
Signature has been broken.	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:01:04
User entered '11 Jan 2021' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:01:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4) Junlin Long (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
DataPoint activated with code reason code Data required.	(b) (4)	03 Mar 2021 14:21:31
Signature has been broken.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User signature succeeded.	Junlin Long (b) (4)	14 Jan 2021 15:09:15
User entered 'No (N)'	(b) (4)	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:21:31
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:20:20
User entered '1'	System	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	03 Mar 2021 14:21:31
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	03 Mar 2021 14:20:20
User entered '1'	System	08 Jan 2021 19:37:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	20 Oct 2020 12:10:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:05
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	03 Mar 2021 14:21:31
DataPoint inactivated with code reason code Data not required.	(b) (4)	03 Mar 2021 14:20:20
User entered '804 (804)'	Junlin Long (b) (4)	03 Mar 2021 14:20:20
DataPoint activated with code reason code Data required.	(b) (4)	08 Jan 2021 19:37:47
DataPoint inactivated with code reason code Data not required.	System	08 Jan 2021 19:36:47
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	08 Jan 2021 19:36:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	20 Oct 2020 12:10:56
	Junlin Long (b) (4)	
	(b) (4)	

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
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)	08 Jan 2021 19:39:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 19:39:49
Data point term sent to Coder	System	08 Jan 2021 19:39:21
User entered 'atorvastatin'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'hypercholesterolemia'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'once daily (QD)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:10:05
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'ae updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:16:06
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:49:00
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:12:45
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:02:23
User entered '1 Jan 2021' reason for change: New Information	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:02:23
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	14 Jan 2021 15:09:15
User entered '2 Jan 2021'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
Signature has been broken.	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:02:23
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:02:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
Signature has been broken.	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:02:23
User entered '11 Jan 2021' reason for change: New Information	(b) (4) Junlin Long (b) (4)	25 Jan 2021 15:02:23
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'No (N)'	Junlin Long (b) (4)	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
User entered '1'	System	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
User entered '1'	System	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:13
User entered '804 (804)'	System	08 Jan 2021 19:38:21

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 21:54:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:54:56
Data point term sent to Coder	System	25 Jan 2021 15:22:12
User entered 'dulcolax'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'prevention of constipation'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '10'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Rectal (RECTAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
User entered empty.	System	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
User entered empty.	System	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:20
User entered empty.	System	25 Jan 2021 15:22:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 07:51:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 07:51:13
Data point term sent to Coder	System	25 Jan 2021 15:23:20
User entered 'heparin'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'prevention of blood clots'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '5000'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Other (OTHER)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'unit'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'other (OTHER)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'every 6 hours'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
User entered empty.	System	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
User entered empty.	System	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:26
User entered empty.	System	25 Jan 2021 15:23:05

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #8 and #9. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:12:59
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #8 and #9. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'according to medical records, conmed line 7, 8 and 9 were given on the same day.' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:25:24
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #8 and #9. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:49:24
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	28 Jan 2021 15:12:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL HYDROCHLORIDE, PRODUCTSYNONYM: TRANDATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:26:47

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'trandate'	Coder Import (b) (4) (b) (4) System Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:47  25 Jan 2021 15:26:23 25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'hypertension'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '10'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
User entered empty.	System	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
User entered empty.	System	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:31
User entered empty.	System	25 Jan 2021 15:26:17

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL HYDROCHLORIDE, PRODUCTSYNONYM: TRANDATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 15:27:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:27:49
Data point term sent to Coder	System	25 Jan 2021 15:27:24
User entered 'trandate'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'hypertension'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
User entered empty.	System	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
User entered empty.	System	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:35
User entered empty.	System	25 Jan 2021 15:27:03

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL HYDROCHLORIDE, PRODUCTSYNONYM: TRANDATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 15:28:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:28:50
Data point term sent to Coder	System	25 Jan 2021 15:28:25
User entered 'trandate'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'hypertension'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '40'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
User entered empty.	System	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
User entered empty.	System	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:39
User entered empty.	System	25 Jan 2021 15:27:51

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 15:30:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 15:30:11
Data point term sent to Coder	System	25 Jan 2021 15:29:25
User entered 'miralax'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'prevention of constipation'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '17'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'g (g)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
User entered empty.	System	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
User entered empty.	System	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:44
User entered empty.	System	25 Jan 2021 15:28:43

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 15:30:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:30:49
Data point term sent to Coder	System	25 Jan 2021 15:30:29
User entered 'senokot'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'prevention of constipation'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '17.2'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'as needed (PRN)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:04
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
User entered empty.	System	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
User entered empty.	System	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:09:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:53:48
User entered empty.	System	25 Jan 2021 15:29:56

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:09:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:25
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:53:01

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	Junlin Long (b) (4)	25 Jan 2021 14:54:50

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'brain ct wo contrast'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:54:50

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:54:50

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:54:50

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:10

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'ct chest wo contrast'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:10

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:10

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:10

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:45

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'head mra wo contrast'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:45

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:45

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:55:45

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:06

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'brain mri wo contrast'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:06

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:06

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:06

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:24

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'chest single view x-ray'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:24

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:24

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:24

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:51

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'echocardiogram'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:51

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:51

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:56:51

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:02

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'ekg'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:02

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:02

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:02

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:10

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '2 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:23

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'carotid duplex'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:23

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:23

US3622211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:09:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:07:46
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	25 Jan 2021 14:57:23

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

**US3622211**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '11/Jan/2021 17:05'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:09:10

**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 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

**US3622211**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:09:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '26/Jan/2021 15:56'	(b) (4) System	26 Jan 2021 15:56:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:09:10

**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 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 17:06:34
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:56:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:09:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '01/Feb/2021 17:06'	(b) (4) System	01 Feb 2021 17:06:43

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:09:10

**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 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:34:34
User entered '1'	(b) (4), (b) (6)	01 Feb 2021 17:06:43

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

**US3622211**

**Folder: SAE USA-US085-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:09:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:09:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '09/Feb/2021 11:34'	(b) (4) System	09 Feb 2021 16:34:45

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:09:10

**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 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:34:45

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'USA-US085-2021-MRNA-1273-P301000001'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Yes (Y)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'No (N)'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Susanne'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Doblecki-Lewis'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '1120 NW 14th Street'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'Miami'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered 'FL'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:05:38
User entered '33136'	System	11 Jan 2021 17:04:04

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:56:37
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
User entered 'US'	(b) (4) System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:09:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 Mar 2021 15:06:06
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:46
	(b) (4)	
User entered '4'	System	09 Feb 2021 16:34:45
Signature has been broken.	System	01 Feb 2021 17:06:43
User entered '3'	System	01 Feb 2021 17:06:43
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:12:45
	(b) (4)	
Signature has been broken.	System	26 Jan 2021 15:56:49
User entered '2'	System	26 Jan 2021 15:56:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:09:15
	(b) (4)	
User entered '1'	System	11 Jan 2021 17:05:49

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:09:10

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered '03/Mar/2021 10:06'	(b) (4) System	03 Mar 2021 15:06:06

US3622211

Folder: SAE USA-US085-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:09:10

**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 12:02:01
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:59:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:06:06