

US3112071 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3112071

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:50:39

Generated On: 09 Jun 2021 15:08:25

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Participant ID

US3112071

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

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US3112071

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:40:45

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Date of Informed Consent (*dd MMM yyyy*) 3 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:40:45

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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) 19 Feb 2021 16:40:45

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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) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	3 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:15 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 16:15
Height ( <i>xxx.x</i> )	69 in
Weight ( <i>xxx.x</i> )	176.8 lb
BMI ( <i>xxx.x</i> )	26.16339 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:40:45

Generated On: 09 Jun 2021 15:08:25

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

SOFTWARE DEVELOPER

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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) 19 Feb 2021 16:40:45

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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) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 100813

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

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) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 16:15
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	077 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	18:09 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 18:09
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

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) 3 AUG 2020

What was the treatment time? (00:00-23:59) 17:38 (24 HR)

Treatment Date and Time (derived) 3 AUG 2020 17:38

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) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 AUG 2020
Collection time (00:00-23:59)	16:40 (24 HR)
Collection date and time (derived)	3 AUG 2020 16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:27	3 AUG 2020 16:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 18:14

PC Open Date & Time

03 AUG 2020 17:58

PC Close Date & Time

03 AUG 2020 20:28



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**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

96.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	03 AUG 2020 22:00
PC Open Date & Time	03 AUG 2020 21:23
PC Close Date & Time	04 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 19:29

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 20:58

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 14:49

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 AUG 2020 18:48

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

09 AUG 2020 21:22

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 18:14

PC Open Date & Time

03 AUG 2020 17:58

PC Close Date & Time

03 AUG 2020 20:28



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**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

03 AUG 2020 22:00

PC Open Date & Time

03 AUG 2020 21:23

PC Close Date & Time

04 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 19:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 20:57

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 14:47

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:47

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 20:08

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 21:22

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**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 ☐



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 18:15
PC Open Date & Time	03 AUG 2020 17:58
PC Close Date & Time	03 AUG 2020 20:28

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**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 ☐

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 22:01
PC Open Date & Time	03 AUG 2020 21:23
PC Close Date & Time	04 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**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 ☒

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 19:31
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:58
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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 ☒



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 14:47
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:48
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 20:09
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 21:23
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3112071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3112071

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

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

Visit date (dd MMM yyyy)	31 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	17:09 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 17:09
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	18:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 18:22
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG



US3112071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 17:51 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 17:51

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

US3112071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

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

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	16:45 (24 HR)
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Collection date and time (derived)	31 AUG 2020 16:45
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US3112071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:14	31 AUG 2020 17:14
Nasopharyngeal Swab 2	No		

US3112071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 31 AUG 2020 18:23

PC Open Date & Time 31 AUG 2020 18:11

PC Close Date & Time 31 AUG 2020 20:41

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	31 AUG 2020 22:14
PC Open Date & Time	31 AUG 2020 21:36
PC Close Date & Time	01 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:11

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 21:27

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**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

97.7 °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

03 SEP 2020 22:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:39

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:14

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:59

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:23

PC Open Date & Time

31 AUG 2020 18:11

PC Close Date & Time

31 AUG 2020 20:41

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 22:15

PC Open Date & Time

31 AUG 2020 21:36

PC Close Date & Time

01 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 16:10

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:28

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 22:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:40

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**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 ☐

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 18:24
PC Open Date & Time	31 AUG 2020 18:11
PC Close Date & Time	31 AUG 2020 20:41

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**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 ☐



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 22:16
PC Open Date & Time	31 AUG 2020 21:36
PC Close Date & Time	01 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 16:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 22:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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 ☒



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:41
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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 ☒

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:00
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3112071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

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

US3112071

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:33:33

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3112071

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:41:47

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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	VISIT3

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	16:16 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 16:16
Temperature ( <i>xxx.x</i> )	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

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.*

US3112071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

16:40 (24 HR)

Collection date and time (derived)

29 SEP 2020 16:40

US3112071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:41:48

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 08:59:44

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 10:37:55

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 09:16:27

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 09:01:44

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 106
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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 13:39:24
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 09:23:14

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 07:49:27

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 08:01:23

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 DEC 2020 08:30:10
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 08:05:25

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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

25 DEC 2020 14:15:41

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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

30 DEC 2020 08:09:38

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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

06 JAN 2021 08:04:37

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 08:54:35

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59



US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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 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	21 JAN 2021 19:57:14
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 JAN 2021 08:09:12
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 08:23:02

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 07:32:10

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

<b>TIMEPOINT</b>	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	19 FEB 2021 20:41:27
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 08:35:58

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 08:02:35

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 08:55:35

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59



US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 229

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 22:04:01

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 10:32:50

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

Date and time of submission

11 APR 2021 20:15:18

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

Date and time of submission

21 APR 2021 19:02:12

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 21:26:42
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59
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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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°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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 JAN 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

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**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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°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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAR 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

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**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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°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 ☐



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**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 ☐

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3112071

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

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

**US3112071**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3112071

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:08:25

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		03 MAR 2021 08:02:56



US3112071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:42:17

Generated On: 09 Jun 2021 15:08:25

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*

US3112071

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:42:17

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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

Visit date (dd MMM yyyy)	1 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 MAR 2021
Time of assessment (00:00-23:59)	16:23 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 16:23
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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.*

US3112071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 1 MAR 2021

Collection time (00:00-23:59) 16:40 (24 HR)

Collection date and time (derived) 1 MAR 2021 16:40

US3112071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3112071

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112071**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

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*



**US3112071**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112071

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:08:25

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"/>

**US3112071**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 15:08:25**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3112071

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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

Visit date (dd MMM yyyy)	1 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3112071

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 22:46:56

Generated On: 09 Jun 2021 15:08:25

Date of updated informed consent (dd MMM yyyy) 1 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 1 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3112071

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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

Collection date (dd MMM yyyy)	1 FEB 2021
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Collection time (00:00-23:59)	15:15 (24 HR)
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Collection date and time (derived)	1 FEB 2021 15:15
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US3112071

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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

Collection date (dd MMM yyyy)	1 FEB 2021
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Collection time (00:00 - 23:59)	14:41
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Collection Date and Time (derived)	1 FEB 2021 14:41
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US3112071

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3112071

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

AEID	
Adverse event	PYELONEPHRITIS
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)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3112071

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

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

US3112071

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

AEID	USA-US062-2021-MRNA-1273-P30 1000008
Adverse event	SEPSIS
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)	18 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)	31 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	21 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PT PRESENTED AT HOSPITAL FOR PAIN WHILE URINATING, AD. PAIN, AND FEVER. WAS ADMITTED TO TREAT FOR PYELONEPHRITIS AND SEPSIS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Data signed:** (b) (4) 19 Mar 2021 20:18:10

**Generated On: 09 Jun 2021 15:08:25**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#) 0

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US3112071

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

AEID	
Adverse event	ALTITUDE SICKNESS
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)	22 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)	22 JAN 2021
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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 19 Mar 2021 20:18:10

Generated On: 09 Jun 2021 15:08:25

AEID	
Adverse event	PROSTATITIS
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)	04 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (7)

Data signed: (b) (4) 19 Mar 2021 20:18:10

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

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

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

Yes ☒

No ☐

---

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

---

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication FLOMAX

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	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)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication TESTOSTERONE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication ANKLE PAIN-BILATERAL

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA VIRUS  
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	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)	18 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)		18 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	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)		22 JAN 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication SEPSIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	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)	18 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)		18 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication PROSTATITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3112071

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3112071

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:08:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:08:25

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 ☐

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

SAEID	USA-US062-2021-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

SAEID	USA-US062-2021-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/JAN/2021 11:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:50:40

Generated On: 09 Jun 2021 15:08:25

SAEID	USA-US062-2021-MRNA-1273-P301000008
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/FEB/2021 15:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3112071 (Prod: Medical Center For Clinical Research - M3 Wake Research)

**US3112071**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:08:25**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:08:57
User entered 'US3112071'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:24:16

US3112071

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:29

US3112071

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:24:17

US3112071

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:29

**US3112071**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'SCRN'	System	03 Aug 2020 23:41:29

US3112071

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:24:18

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '55'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31



**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'YEARS'	System	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered '55'	System	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Male (M)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'I'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

US3112071

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31



**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

US3112071

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:08:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

**US3112071**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:08:25**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:31

US3112071

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:08:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'Aug 2020'	System	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered '2020'	System	03 Aug 2020 23:41:48



**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Amendment 1 (1)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:48

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:24:17

**US3112071**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:08:25**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'I'	System	03 Aug 2020 23:41:53

US3112071

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Aug 2020 23:41:53



US3112071

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:08:25

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 08:52:15
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Med HX updated' (Site from DM).	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:06
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:47:21
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:44:41

US3112071

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:08:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:56:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:56:43
Data point term sent to Coder	System	03 Sep 2020 19:55:54
User entered 'Benign prostatic hyperplasia'	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'Jan 2015'	System	03 Sep 2020 19:54:57



**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered '2015'	System	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered empty.	System	03 Sep 2020 19:54:57

**US3112071**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered empty.	System	03 Sep 2020 19:54:57

US3112071

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:08:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 23:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 23:57:43
Data point term sent to Coder	System	03 Sep 2020 23:56:31
User entered 'Bilateral ankle pain'	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'UN Aug 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29



**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'Aug 2020'	System	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered '2020'	System	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered empty.	System	03 Sep 2020 23:56:29

**US3112071**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered empty.	System	03 Sep 2020 23:56:29

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '16:15'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52



**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered '3 Aug 2020 16:15'	System	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '69' in	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52
DataPoint set to visible.	System	03 Aug 2020 23:41:53

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '176.8' lb	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52
DataPoint set to visible.	System	03 Aug 2020 23:41:53

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
Amendment Manager: User entered '26.16339'	System	16 Sep 2020 23:41:59
User entered '26.2'	System	04 Aug 2020 17:45:52
DataPoint set to visible.	System	03 Aug 2020 23:41:53

**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'kg/m2'	System	04 Aug 2020 17:45:52
DataPoint set to visible.	System	03 Aug 2020 23:41:53

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 08:51:58
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	03 Sep 2020 19:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	03 Sep 2020 19:50:27
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 17:20:58
User entered '98.4' F	Karen Mylerberg (b) (4) (b) (4)	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	03 Sep 2020 19:50:27
User entered 'Oral (Oral)'	(b) (4)	
	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52
	(b) (4)	

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52



US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 19:50:27
User entered '56'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'bpm'	System	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 19:50:27
User entered '16'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'breaths/min'	System	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 19:50:27
User entered '140'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'mmHg'	System	04 Aug 2020 17:45:52

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 19:50:27
User entered '077'	Karen Mylerberg (b) (4)	04 Aug 2020 17:45:52

**US3112071**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User entered 'mmHg'	System	04 Aug 2020 17:45:52



US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49

US3112071

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49

**US3112071**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:08:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:46:01

US3112071

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:23:58
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 00:57:07
User entered '3 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	04 Aug 2020 17:46:01

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08



US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08



US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'Software developer'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

**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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

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)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered 'I'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08



US3112071

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:08:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:56:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:40:46
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:08

US3112071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:22

US3112071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:22

US3112071

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:22

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'VISIT1'	System	04 Aug 2020 17:47:22

US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:39:18

US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:52:17
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:52:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 23:39:18
User entered '100813' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:39:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:39:18



US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:37

US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:37

US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:37

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:08:25**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:37

US3112071

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:08:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:47:37

US3112071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

US3112071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

US3112071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:15'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '3 Aug 2020 16:15'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '98.4' F	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

US3112071

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45



**US3112071**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:08:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '56'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'bpm'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'breaths/min'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '140'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '077'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:08:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 13:24:32
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 17:51:45
User entered '18:09'	Karen Mylerberg (b) (4) (b) (4)	04 Aug 2020 17:51:45

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '3 Aug 2020 18:09'	System	04 Aug 2020 17:51:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '97.9' F	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '60'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'bpm'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '18'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'breaths/min'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '138'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '076'	Karen Mylerberg (b) (4)	04 Aug 2020 17:51:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	04 Aug 2020 17:51:45

US3112071

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:46

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	(b) (4) Matthew Musikanth	04 Aug 2020 00:40:43
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Matthew Musikanth (b) (4)	04 Aug 2020 00:40:43



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Matthew Musikanth (b) (4)	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '17:38'	Matthew Musikanth (b) (4)	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '3 Aug 2020 17:38'	System	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	04 Aug 2020 00:40:43

US3112071

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'ONCE'	System	04 Aug 2020 00:40:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 00:40:43

US3112071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:18



US3112071

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:18

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:40'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:18

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '3 Aug 2020 16:40'	System	04 Aug 2020 17:48:18

US3112071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '3 Aug 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

US3112071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:27'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '3 Aug 2020 16:27'	System	04 Aug 2020 17:48:35



US3112071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

US3112071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

US3112071

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:35

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered empty.	System	04 Aug 2020 17:48:35

US3112071

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:48:40

**US3112071**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	04 Aug 2020 17:48:40

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:13:45', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4778036e-ea21-4509-be86-425068a68a52'	System	04 Aug 2020 01:14:08
User entered 'Yes (Y)'	System	04 Aug 2020 01:14:08



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:13:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4778036e-ea21-4509-be86-425068a68a52'	System	04 Aug 2020 01:14:08
User entered '97.9'	System	04 Aug 2020 01:14:08

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:13:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4778036e-ea21-4509-be86-425068a68a52'	System	04 Aug 2020 01:14:08
User entered 'No (N)'	System	04 Aug 2020 01:14:08

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4778036e-ea21-4509-be86-425068a68a52'	System	04 Aug 2020 01:14:08
User entered '03 Aug 2020 18:14'	System	04 Aug 2020 01:14:08

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 17:58'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 20:28'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:21', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '55eef6f9-70ae-4d07-9eca-107c04c29c35'	System	04 Aug 2020 05:00:45
User entered 'Yes (Y)'	System	04 Aug 2020 05:00:45

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:34', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '55eef6f9-70ae-4d07-9eca-107c04c29c35'	System	04 Aug 2020 05:00:45
User entered '96.9'	System	04 Aug 2020 05:00:45



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '55eef6f9-70ae-4d07-9eca-107c04c29c35'	System	04 Aug 2020 05:00:45
User entered 'No (N)'	System	04 Aug 2020 05:00:45

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:42', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '55eef6f9-70ae-4d07-9eca-107c04c29c35'	System	04 Aug 2020 05:00:45
User entered '03 Aug 2020 22:00'	System	04 Aug 2020 05:00:45

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 21:23'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 2'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:27:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18503c33-2e91-44ed-a20f-085bc81b716f'	System	05 Aug 2020 02:29:05
User entered 'Yes (Y)'	System	05 Aug 2020 02:29:05

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:28:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18503c33-2e91-44ed-a20f-085bc81b716f'	System	05 Aug 2020 02:29:05
User entered '97.0'	System	05 Aug 2020 02:29:05

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:29:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18503c33-2e91-44ed-a20f-085bc81b716f'	System	05 Aug 2020 02:29:05
User entered 'No (N)'	System	05 Aug 2020 02:29:05



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:29:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18503c33-2e91-44ed-a20f-085bc81b716f'	System	05 Aug 2020 02:29:05
User entered '04 Aug 2020 19:29'	System	05 Aug 2020 02:29:05

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 3'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fc117585-f103-4445-be75-2028ced0eba6'	System	06 Aug 2020 03:58:43
User entered 'Yes (Y)'	System	06 Aug 2020 03:58:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:15', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fc117585-f103-4445-be75-2028ced0eba6'	System	06 Aug 2020 03:58:43
User entered '97.6'	System	06 Aug 2020 03:58:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:36', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fc117585-f103-4445-be75-2028ced0eba6'	System	06 Aug 2020 03:58:43
User entered 'No (N)'	System	06 Aug 2020 03:58:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fc117585-f103-4445-be75-2028ced0eba6'	System	06 Aug 2020 03:58:43
User entered '05 Aug 2020 20:58'	System	06 Aug 2020 03:58:43



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 4'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:48:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b450fe2e-7b80-4c90-ae1a-1a0b737ce36e'	System	06 Aug 2020 21:49:09
User entered 'Yes (Y)'	System	06 Aug 2020 21:49:09

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:48:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b450fe2e-7b80-4c90-ae1a-1a0b737ce36e'	System	06 Aug 2020 21:49:09
User entered '98.6'	System	06 Aug 2020 21:49:09

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:49:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b450fe2e-7b80-4c90-ae1a-1a0b737ce36e'	System	06 Aug 2020 21:49:09
User entered 'No (N)'	System	06 Aug 2020 21:49:09

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:49:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b450fe2e-7b80-4c90-ae1a-1a0b737ce36e'	System	06 Aug 2020 21:49:09
User entered '06 Aug 2020 14:49'	System	06 Aug 2020 21:49:09

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 00:40:43



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 5'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '972a4b5b-76b5-499e-a785-71168e4f2516'	System	08 Aug 2020 01:48:42
User entered 'Yes (Y)'	System	08 Aug 2020 01:48:42

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '972a4b5b-76b5-499e-a785-71168e4f2516' User entered '97.8'	System	08 Aug 2020 01:48:42
	System	08 Aug 2020 01:48:42

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '972a4b5b-76b5-499e-a785-71168e4f2516'	System	08 Aug 2020 01:48:42
User entered 'No (N)'	System	08 Aug 2020 01:48:42

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '972a4b5b-76b5-499e-a785-71168e4f2516'	System	08 Aug 2020 01:48:42
User entered '07 Aug 2020 18:48'	System	08 Aug 2020 01:48:42

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 00:40:43



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 6'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3013b9d1-c297-476b-b8e3-724ffbe379b0'	System	09 Aug 2020 03:08:29
User entered 'Yes (Y)'	System	09 Aug 2020 03:08:29

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:18', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3013b9d1-c297-476b-b8e3-724ffbe379b0' User entered '97.1'	System	09 Aug 2020 03:08:29
	System	09 Aug 2020 03:08:29

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3013b9d1-c297-476b-b8e3-724ffbe379b0'	System	09 Aug 2020 03:08:29
User entered 'No (N)'	System	09 Aug 2020 03:08:29

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:26', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3013b9d1-c297-476b-b8e3-724ffbe379b0'	System	09 Aug 2020 03:08:29
User entered '08 Aug 2020 20:08'	System	09 Aug 2020 03:08:29

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 7'	System	04 Aug 2020 00:40:43



US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:33', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79a08b9a-0ce4-4abc-8869-c8ec84d7b55b'	System	10 Aug 2020 04:22:48
User entered 'Yes (Y)'	System	10 Aug 2020 04:22:48

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79a08b9a-0ce4-4abc-8869-c8ec84d7b55b'	System	10 Aug 2020 04:22:48
User entered '97.5'	System	10 Aug 2020 04:22:48

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:42', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79a08b9a-0ce4-4abc-8869-c8ec84d7b55b'	System	10 Aug 2020 04:22:48
User entered 'No (N)'	System	10 Aug 2020 04:22:48

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79a08b9a-0ce4-4abc-8869-c8ec84d7b55b'	System	10 Aug 2020 04:22:48
User entered '09 Aug 2020 21:22'	System	10 Aug 2020 04:22:48

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f9535c45-d437-4843-ad65-1d3a836494de'	System	04 Aug 2020 01:15:03
User entered 'None (1)'	System	04 Aug 2020 01:15:03



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f9535c45-d437-4843-ad65-1d3a836494de'	System	04 Aug 2020 01:15:03
User entered 'No (N)'	System	04 Aug 2020 01:15:03

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f9535c45-d437-4843-ad65-1d3a836494de'	System	04 Aug 2020 01:15:03
User entered 'No (N)'	System	04 Aug 2020 01:15:03

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f9535c45-d437-4843-ad65-1d3a836494de'	System	04 Aug 2020 01:15:03
User entered 'None (1)'	System	04 Aug 2020 01:15:03

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:14:59', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f9535c45-d437-4843-ad65-1d3a836494de'	System	04 Aug 2020 01:15:03
User entered '03 Aug 2020 18:14'	System	04 Aug 2020 01:15:03

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 17:58'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 20:28'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T21:59:05', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '143c90c4-7b45-4610-ba85-0bba538f7c36'	System	04 Aug 2020 05:00:19
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 05:00:19



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T21:59:33', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '143c90c4-7b45-4610-ba85-0bba538f7c36'	System	04 Aug 2020 05:00:19
User entered 'No (N)'	System	04 Aug 2020 05:00:19

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T21:59:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '143c90c4-7b45-4610-ba85-0bba538f7c36'	System	04 Aug 2020 05:00:19
User entered 'No (N)'	System	04 Aug 2020 05:00:19

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '143c90c4-7b45-4610-ba85-0bba538f7c36'	System	04 Aug 2020 05:00:19
User entered 'None (1)'	System	04 Aug 2020 05:00:19

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:14', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '143c90c4-7b45-4610-ba85-0bba538f7c36'	System	04 Aug 2020 05:00:19
User entered '03 Aug 2020 22:00'	System	04 Aug 2020 05:00:19

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 21:23'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 2'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:29:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd7c2c4ed-77b8-40dd-b7bf-6d8d3eb44215'	System	05 Aug 2020 02:30:18
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 02:30:18



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:29:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd7c2c4ed-77b8-40dd-b7bf-6d8d3eb44215'	System	05 Aug 2020 02:30:18
User entered 'No (N)'	System	05 Aug 2020 02:30:18

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:29:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd7c2c4ed-77b8-40dd-b7bf-6d8d3eb44215'	System	05 Aug 2020 02:30:18
User entered 'No (N)'	System	05 Aug 2020 02:30:18

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:30:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd7c2c4ed-77b8-40dd-b7bf-6d8d3eb44215'	System	05 Aug 2020 02:30:18
User entered 'None (1)'	System	05 Aug 2020 02:30:18

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:30:15', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd7c2c4ed-77b8-40dd-b7bf-6d8d3eb44215'	System	05 Aug 2020 02:30:18
User entered '04 Aug 2020 19:30'	System	05 Aug 2020 02:30:18

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 3'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:56:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8cda9ff3-eb5b-4996-b06f-65dc56e9d9bc'	System	06 Aug 2020 03:57:22
User entered 'None (1)'	System	06 Aug 2020 03:57:22



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:56:50', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8cda9ff3-eb5b-4996-b06f-65dc56e9d9bc'	System	06 Aug 2020 03:57:22
User entered 'No (N)'	System	06 Aug 2020 03:57:22

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8cda9ff3-eb5b-4996-b06f-65dc56e9d9bc'	System	06 Aug 2020 03:57:22
User entered 'No (N)'	System	06 Aug 2020 03:57:22

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8cda9ff3-eb5b-4996-b06f-65dc56e9d9bc'	System	06 Aug 2020 03:57:22
User entered 'None (1)'	System	06 Aug 2020 03:57:22

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8cda9ff3-eb5b-4996-b06f-65dc56e9d9bc'	System	06 Aug 2020 03:57:22
User entered '05 Aug 2020 20:57'	System	06 Aug 2020 03:57:22

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 4'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:46:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3f467a5-0957-4b3e-890d-a0d454b0cc41'	System	06 Aug 2020 21:47:21
User entered 'None (1)'	System	06 Aug 2020 21:47:21



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:46:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3f467a5-0957-4b3e-890d-a0d454b0cc41'	System	06 Aug 2020 21:47:21
User entered 'No (N)'	System	06 Aug 2020 21:47:21

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:01', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3f467a5-0957-4b3e-890d-a0d454b0cc41'	System	06 Aug 2020 21:47:21
User entered 'No (N)'	System	06 Aug 2020 21:47:21

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3f467a5-0957-4b3e-890d-a0d454b0cc41'	System	06 Aug 2020 21:47:21
User entered 'None (1)'	System	06 Aug 2020 21:47:21

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3f467a5-0957-4b3e-890d-a0d454b0cc41'	System	06 Aug 2020 21:47:21
User entered '06 Aug 2020 14:47'	System	06 Aug 2020 21:47:21

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 5'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:34', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '06c374a2-f49a-4794-8a61-949af4402a00'	System	08 Aug 2020 01:47:53
User entered 'None (1)'	System	08 Aug 2020 01:47:53



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '06c374a2-f49a-4794-8a61-949af4402a00'	System	08 Aug 2020 01:47:53
User entered 'No (N)'	System	08 Aug 2020 01:47:53

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '06c374a2-f49a-4794-8a61-949af4402a00'	System	08 Aug 2020 01:47:53
User entered 'No (N)'	System	08 Aug 2020 01:47:53

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:45', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '06c374a2-f49a-4794-8a61-949af4402a00'	System	08 Aug 2020 01:47:53
User entered 'None (1)'	System	08 Aug 2020 01:47:53

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:48', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '06c374a2-f49a-4794-8a61-949af4402a00'	System	08 Aug 2020 01:47:53
User entered '07 Aug 2020 18:47'	System	08 Aug 2020 01:47:53

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 6'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18dbdb98-461f-4871-b6cf-87d5ed6cd2e8'	System	09 Aug 2020 03:08:54
User entered 'None (1)'	System	09 Aug 2020 03:08:54



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18dbdb98-461f-4871-b6cf-87d5ed6cd2e8'	System	09 Aug 2020 03:08:54
User entered 'No (N)'	System	09 Aug 2020 03:08:54

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18dbdb98-461f-4871-b6cf-87d5ed6cd2e8'	System	09 Aug 2020 03:08:54
User entered 'No (N)'	System	09 Aug 2020 03:08:54

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:50', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18dbdb98-461f-4871-b6cf-87d5ed6cd2e8'	System	09 Aug 2020 03:08:54
User entered 'None (1)'	System	09 Aug 2020 03:08:54

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:08:52', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '18dbdb98-461f-4871-b6cf-87d5ed6cd2e8'	System	09 Aug 2020 03:08:54
User entered '08 Aug 2020 20:08'	System	09 Aug 2020 03:08:54

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 7'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:01', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '58d6ce3b-eebd-4e93-919b-ef63d23298e5'	System	10 Aug 2020 04:22:26
User entered 'None (1)'	System	10 Aug 2020 04:22:26



US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '58d6ce3b-eebd-4e93-919b-ef63d23298e5'	System	10 Aug 2020 04:22:26
User entered 'No (N)'	System	10 Aug 2020 04:22:26

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '58d6ce3b-eebd-4e93-919b-ef63d23298e5'	System	10 Aug 2020 04:22:26
User entered 'No (N)'	System	10 Aug 2020 04:22:26

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '58d6ce3b-eebd-4e93-919b-ef63d23298e5'	System	10 Aug 2020 04:22:26
User entered 'None (1)'	System	10 Aug 2020 04:22:26

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:21', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '58d6ce3b-eebd-4e93-919b-ef63d23298e5'	System	10 Aug 2020 04:22:26
User entered '09 Aug 2020 21:22'	System	10 Aug 2020 04:22:26

US3112071

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered 'None (0)'	System	04 Aug 2020 01:15:39



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered 'None (0)'	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered 'None (0)'	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:21', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b' User entered 'None (0)'	System	04 Aug 2020 01:15:39
	System	04 Aug 2020 01:15:39

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:08:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b' User entered 'None (0)'	System	04 Aug 2020 01:15:39
	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:25', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered 'None (0)'	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:32', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered 'No (N)'	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T18:15:36', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5cedc668-ed73-4c90-bec2-35ad0190d82b'	System	04 Aug 2020 01:15:39
User entered '03 Aug 2020 18:15'	System	04 Aug 2020 01:15:39

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 17:58'	System	04 Aug 2020 00:40:43



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 20:28'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:08:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:00:56', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:01:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:01:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:01:06', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'None (0)'	System	04 Aug 2020 05:01:21



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:01:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered 'No (N)'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-03T22:01:18', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8f5afa0a-43d4-45f3-8c72-987b5ed0fbda'	System	04 Aug 2020 05:01:21
User entered '03 Aug 2020 22:01'	System	04 Aug 2020 05:01:21

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Aug 2020 21:23'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 2'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:30:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'No interference with activity (1)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:30:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'None (0)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:30:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'None (0)'	System	05 Aug 2020 02:31:25



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:31:01', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'None (0)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:31:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'None (0)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:31:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'None (0)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:31:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered 'No (N)'	System	05 Aug 2020 02:31:25

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-04T19:31:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ca03d10-59fe-42da-82b3-ed23902d6eff'	System	05 Aug 2020 02:31:25
User entered '04 Aug 2020 19:31'	System	05 Aug 2020 02:31:25

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 3'	System	04 Aug 2020 00:40:43



**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:25', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:57:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'None (0)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:01', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered 'No (N)'	System	06 Aug 2020 03:58:07

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-05T20:58:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8ed30fc3-3b43-4a37-bac1-0966e5c48eb6'	System	06 Aug 2020 03:58:07
User entered '05 Aug 2020 20:58'	System	06 Aug 2020 03:58:07



**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 4'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'None (0)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:19', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'None (0)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'None (0)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:26', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'None (0)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:29', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'None (0)'	System	06 Aug 2020 21:47:55



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'No interference with activity (1)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:42', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered 'No (N)'	System	06 Aug 2020 21:47:55

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-06T14:47:52', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '04a209f3-a3df-4cc0-b0f8-d61c4fdd11c4'	System	06 Aug 2020 21:47:55
User entered '06 Aug 2020 14:47'	System	06 Aug 2020 21:47:55

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 5'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:47:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:02', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'None (0)'	System	08 Aug 2020 01:48:11

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered 'No (N)'	System	08 Aug 2020 01:48:11

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-07T18:48:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '23d8a284-8756-4107-9945-bcb40df41f96'	System	08 Aug 2020 01:48:11
User entered '07 Aug 2020 18:48'	System	08 Aug 2020 01:48:11

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 00:40:43



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 6'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:02', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'None (0)'	System	09 Aug 2020 03:09:23

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered 'No (N)'	System	09 Aug 2020 03:09:23



US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-08T20:09:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7cf01c58-960e-4ef6-9e39-c32432855505'	System	09 Aug 2020 03:09:23
User entered '08 Aug 2020 20:09'	System	09 Aug 2020 03:09:23

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 7'	System	04 Aug 2020 00:40:43

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:49', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'None (0)'	System	10 Aug 2020 04:23:08

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'None (0)'	System	10 Aug 2020 04:23:08

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:54', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'None (0)'	System	10 Aug 2020 04:23:08

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:56', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1' User entered 'None (0)'	System	10 Aug 2020 04:23:08
	System	10 Aug 2020 04:23:08



**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:22:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'None (0)'	System	10 Aug 2020 04:23:08

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:23:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'None (0)'	System	10 Aug 2020 04:23:08

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:23:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered 'No (N)'	System	10 Aug 2020 04:23:08

US3112071

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-09T21:23:06', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ebbd2216-b383-4c64-b890-1ad3d47558d1'	System	10 Aug 2020 04:23:08
User entered '09 Aug 2020 21:23'	System	10 Aug 2020 04:23:08

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:09:23

US3112071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered '10 Aug 2020'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:09:23



US3112071

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Contact Made (CONTACT MADE)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:09:23

**US3112071**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:09:23

US3112071

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:09:29

**US3112071**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	10 Aug 2020 17:09:29

**US3112071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:06:50

**US3112071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:06:50

**US3112071**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:06:50

US3112071

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:06:50



US3112071

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:06:55

**US3112071**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	19 Aug 2020 22:06:55

**US3112071**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:18:13

US3112071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:18:13

US3112071

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:18:13

**US3112071**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:18:13

US3112071

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:56:49

**US3112071**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	01 Sep 2020 00:56:49



**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:07

US3112071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:07

US3112071

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:07

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'VISIT2'	System	01 Sep 2020 00:57:07

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '17:09'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42



US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '31 Aug 2020 17:09'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '99.0' F	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '61'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'bpm'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'breaths/min'	System	03 Sep 2020 19:52:42



US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '120'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '069'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '18:22'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42



US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '31 Aug 2020 18:22'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '97.9' F	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:08:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '58'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'bpm'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'breaths/min'	System	03 Sep 2020 19:52:42



US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '122'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '066'	Karen Mylerberg (b) (4)	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	03 Sep 2020 19:52:42

US3112071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	03 Sep 2020 19:53:03

US3112071

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 21:17:49
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:03

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27



US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '17:51'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '31 Aug 2020 17:51'	System	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'ONCE'	System	01 Sep 2020 00:57:27

US3112071

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:08:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 00:57:27



US3112071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:22

US3112071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:22

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:45'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:22

US3112071

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '31 Aug 2020 16:45'	System	03 Sep 2020 19:53:22

US3112071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '31 Aug 2020'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

US3112071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '17:14'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40



**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '31 Aug 2020 17:14'	System	03 Sep 2020 19:53:40

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

US3112071

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:08:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	03 Sep 2020 19:53:40

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered empty.	System	03 Sep 2020 19:53:40

US3112071

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 00:57:32

**US3112071**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	01 Sep 2020 00:57:32

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:22:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '57ed029a-620c-45f3-a49d-5a3d15ddf567'	System	01 Sep 2020 01:23:15
User entered 'Yes (Y)'	System	01 Sep 2020 01:23:15

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:05', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '57ed029a-620c-45f3-a49d-5a3d15ddf567' User entered '97.9'	System	01 Sep 2020 01:23:15
	System	01 Sep 2020 01:23:15

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:08', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '57ed029a-620c-45f3-a49d-5a3d15ddf567'	System	01 Sep 2020 01:23:15
User entered 'No (N)'	System	01 Sep 2020 01:23:15

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '57ed029a-620c-45f3-a49d-5a3d15ddf567'	System	01 Sep 2020 01:23:15
User entered '31 Aug 2020 18:23'	System	01 Sep 2020 01:23:15

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 18:11'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 20:41'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:14:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '63c5cdc6-5c4a-4803-bf1a-cefff7d977ff'	System	01 Sep 2020 05:14:31
User entered 'Yes (Y)'	System	01 Sep 2020 05:14:31



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:14:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '63c5cdc6-5c4a-4803-bf1a-cefff7d977ff' User entered '97.1'	System	01 Sep 2020 05:14:31
	System	01 Sep 2020 05:14:31

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:14:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '63c5cdc6-5c4a-4803-bf1a-cefff7d977ff'	System	01 Sep 2020 05:14:31
User entered 'No (N)'	System	01 Sep 2020 05:14:31

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:14:25', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '63c5cdc6-5c4a-4803-bf1a-cefff7d977ff'	System	01 Sep 2020 05:14:31
User entered '31 Aug 2020 22:14'	System	01 Sep 2020 05:14:31

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 21:36'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 2'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79450654-76e1-4ad2-b7a9-e4face2449ca'	System	01 Sep 2020 23:11:52
User entered 'Yes (Y)'	System	01 Sep 2020 23:11:52

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79450654-76e1-4ad2-b7a9-e4face2449ca'	System	01 Sep 2020 23:11:52
User entered '99.9'	System	01 Sep 2020 23:11:52



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79450654-76e1-4ad2-b7a9-e4face2449ca'	System	01 Sep 2020 23:11:52
User entered 'No (N)'	System	01 Sep 2020 23:11:52

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:11:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '79450654-76e1-4ad2-b7a9-e4face2449ca'	System	01 Sep 2020 23:11:52
User entered '01 Sep 2020 16:11'	System	01 Sep 2020 23:11:52

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 3'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:26:41', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1786fe5c-e024-46ca-9ea0-ce8f9f4ca246'	System	03 Sep 2020 04:27:09
User entered 'Yes (Y)'	System	03 Sep 2020 04:27:09

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:26:49', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1786fe5c-e024-46ca-9ea0-ce8f9f4ca246'	System	03 Sep 2020 04:27:09
User entered '99.0'	System	03 Sep 2020 04:27:09

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:26:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1786fe5c-e024-46ca-9ea0-ce8f9f4ca246'	System	03 Sep 2020 04:27:09
User entered 'No (N)'	System	03 Sep 2020 04:27:09



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:27:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1786fe5c-e024-46ca-9ea0-ce8f9f4ca246'	System	03 Sep 2020 04:27:09
User entered '02 Sep 2020 21:27'	System	03 Sep 2020 04:27:09

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 4'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:36:28', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '332f5247-f232-46dd-8c10-26a21cf078d8'	System	04 Sep 2020 05:36:43
User entered 'Yes (Y)'	System	04 Sep 2020 05:36:43

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:36:34', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '332f5247-f232-46dd-8c10-26a21cf078d8'	System	04 Sep 2020 05:36:43
User entered '97.7'	System	04 Sep 2020 05:36:43

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:36:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '332f5247-f232-46dd-8c10-26a21cf078d8'	System	04 Sep 2020 05:36:43
User entered 'No (N)'	System	04 Sep 2020 05:36:43

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:36:41', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '332f5247-f232-46dd-8c10-26a21cf078d8'	System	04 Sep 2020 05:36:43
User entered '03 Sep 2020 22:36'	System	04 Sep 2020 05:36:43



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 5'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:39:29', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '741bfe4c-9b88-4643-810f-0fb9125cfbfc'	System	05 Sep 2020 03:39:54
User entered 'Yes (Y)'	System	05 Sep 2020 03:39:54

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:39:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '741bfe4c-9b88-4643-810f-0fb9125cfbfc'	System	05 Sep 2020 03:39:54
User entered '98.0'	System	05 Sep 2020 03:39:54

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:39:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '741bfe4c-9b88-4643-810f-0fb9125cfbfc'	System	05 Sep 2020 03:39:54
User entered 'No (N)'	System	05 Sep 2020 03:39:54

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:39:49', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '741bfe4c-9b88-4643-810f-0fb9125cfbfc'	System	05 Sep 2020 03:39:54
User entered '04 Sep 2020 20:39'	System	05 Sep 2020 03:39:54

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 6'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:14:41', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd46387fa-cdf7-4628-adf8-f93bfc3bc821'	System	06 Sep 2020 04:14:56
User entered 'Yes (Y)'	System	06 Sep 2020 04:14:56

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:14:47', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd46387fa-cdf7-4628-adf8-f93bfc3bc821'	System	06 Sep 2020 04:14:56
User entered '97.0'	System	06 Sep 2020 04:14:56

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:14:50', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd46387fa-cdf7-4628-adf8-f93bfc3bc821'	System	06 Sep 2020 04:14:56
User entered 'No (N)'	System	06 Sep 2020 04:14:56

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:14:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd46387fa-cdf7-4628-adf8-f93bfc3bc821'	System	06 Sep 2020 04:14:56
User entered '05 Sep 2020 21:14'	System	06 Sep 2020 04:14:56

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 7'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7e36b27d-9e85-467c-9ef2-164344390151'	System	07 Sep 2020 00:59:48
User entered 'Yes (Y)'	System	07 Sep 2020 00:59:48

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7e36b27d-9e85-467c-9ef2-164344390151' User entered '98.2'	System	07 Sep 2020 00:59:48
	System	07 Sep 2020 00:59:48

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7e36b27d-9e85-467c-9ef2-164344390151'	System	07 Sep 2020 00:59:48
User entered 'No (N)'	System	07 Sep 2020 00:59:48

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:43', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7e36b27d-9e85-467c-9ef2-164344390151'	System	07 Sep 2020 00:59:48
User entered '06 Sep 2020 17:59'	System	07 Sep 2020 00:59:48

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '39150eaa-3d34-46ee-a447-e927787106ea'	System	01 Sep 2020 01:23:52
User entered 'None (1)'	System	01 Sep 2020 01:23:52

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:32', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '39150eaa-3d34-46ee-a447-e927787106ea'	System	01 Sep 2020 01:23:52
User entered 'No (N)'	System	01 Sep 2020 01:23:52

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '39150eaa-3d34-46ee-a447-e927787106ea'	System	01 Sep 2020 01:23:52
User entered 'No (N)'	System	01 Sep 2020 01:23:52

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '39150eaa-3d34-46ee-a447-e927787106ea'	System	01 Sep 2020 01:23:52
User entered 'None (1)'	System	01 Sep 2020 01:23:52

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:49', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '39150eaa-3d34-46ee-a447-e927787106ea'	System	01 Sep 2020 01:23:52
User entered '31 Aug 2020 18:23'	System	01 Sep 2020 01:23:52

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 18:11'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 20:41'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:14:34', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '2fd3ab19-a606-4138-9124-3947e1048e6d'	System	01 Sep 2020 05:15:53
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 05:15:53

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:15:26', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '2fd3ab19-a606-4138-9124-3947e1048e6d'	System	01 Sep 2020 05:15:53
User entered 'No (N)'	System	01 Sep 2020 05:15:53

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:15:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '2fd3ab19-a606-4138-9124-3947e1048e6d'	System	01 Sep 2020 05:15:53
User entered 'No (N)'	System	01 Sep 2020 05:15:53

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:15:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '2fd3ab19-a606-4138-9124-3947e1048e6d'	System	01 Sep 2020 05:15:53
User entered 'None (1)'	System	01 Sep 2020 05:15:53

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:15:48', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '2fd3ab19-a606-4138-9124-3947e1048e6d'	System	01 Sep 2020 05:15:53
User entered '31 Aug 2020 22:15'	System	01 Sep 2020 05:15:53

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 21:36'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 2'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:09:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d'	System	01 Sep 2020 23:10:33
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:09:33', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d'	System	01 Sep 2020 23:10:33
User entered 'No (N)'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:09:41', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d'	System	01 Sep 2020 23:10:33
User entered 'Yes (Y)'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:16', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d' User entered '40'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:25', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d'	System	01 Sep 2020 23:10:33
User entered 'None (1)'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:10:29', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9697fa94-3d03-4e8a-be0e-abf1427bab4d'	System	01 Sep 2020 23:10:33
User entered '01 Sep 2020 16:10'	System	01 Sep 2020 23:10:33

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 3'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:14', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1c74a8ac-d3e0-445e-8263-cfb468ed6787'	System	03 Sep 2020 04:28:34
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 04:28:34

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1c74a8ac-d3e0-445e-8263-cfb468ed6787'	System	03 Sep 2020 04:28:34
User entered 'No (N)'	System	03 Sep 2020 04:28:34

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1c74a8ac-d3e0-445e-8263-cfb468ed6787'	System	03 Sep 2020 04:28:34
User entered 'No (N)'	System	03 Sep 2020 04:28:34

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1c74a8ac-d3e0-445e-8263-cfb468ed6787'	System	03 Sep 2020 04:28:34
User entered 'None (1)'	System	03 Sep 2020 04:28:34

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1c74a8ac-d3e0-445e-8263-cfb468ed6787'	System	03 Sep 2020 04:28:34
User entered '02 Sep 2020 21:28'	System	03 Sep 2020 04:28:34

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 4'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:36:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '99a8738a-91dc-43c5-bace-21c6aefd5a79'	System	04 Sep 2020 05:37:28
User entered 'None (1)'	System	04 Sep 2020 05:37:28

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '99a8738a-91dc-43c5-bace-21c6aefd5a79'	System	04 Sep 2020 05:37:28
User entered 'No (N)'	System	04 Sep 2020 05:37:28

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '99a8738a-91dc-43c5-bace-21c6aefd5a79'	System	04 Sep 2020 05:37:28
User entered 'No (N)'	System	04 Sep 2020 05:37:28

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '99a8738a-91dc-43c5-bace-21c6aefd5a79'	System	04 Sep 2020 05:37:28
User entered 'None (1)'	System	04 Sep 2020 05:37:28

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:26', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '99a8738a-91dc-43c5-bace-21c6aefd5a79'	System	04 Sep 2020 05:37:28
User entered '03 Sep 2020 22:37'	System	04 Sep 2020 05:37:28

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 5'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:39:59', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0e2af70-b3f4-4f63-864d-e38d01aebd48'	System	05 Sep 2020 03:41:01
User entered 'None (1)'	System	05 Sep 2020 03:41:01

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:40:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0e2af70-b3f4-4f63-864d-e38d01aebd48'	System	05 Sep 2020 03:41:01
User entered 'No (N)'	System	05 Sep 2020 03:41:01

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:40:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0e2af70-b3f4-4f63-864d-e38d01aebd48'	System	05 Sep 2020 03:41:01
User entered 'No (N)'	System	05 Sep 2020 03:41:01

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:40:34', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0e2af70-b3f4-4f63-864d-e38d01aebd48'	System	05 Sep 2020 03:41:01
User entered 'None (1)'	System	05 Sep 2020 03:41:01

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:40:59', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0e2af70-b3f4-4f63-864d-e38d01aebd48'	System	05 Sep 2020 03:41:01
User entered '04 Sep 2020 20:40'	System	05 Sep 2020 03:41:01

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 6'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:14:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b6c739a7-e4e1-4dd2-93ba-005f4aeada5a'	System	06 Sep 2020 04:15:32
User entered 'None (1)'	System	06 Sep 2020 04:15:32

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b6c739a7-e4e1-4dd2-93ba-005f4aeada5a'	System	06 Sep 2020 04:15:32
User entered 'No (N)'	System	06 Sep 2020 04:15:32

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:16', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b6c739a7-e4e1-4dd2-93ba-005f4aeada5a'	System	06 Sep 2020 04:15:32
User entered 'No (N)'	System	06 Sep 2020 04:15:32

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b6c739a7-e4e1-4dd2-93ba-005f4aeada5a'	System	06 Sep 2020 04:15:32
User entered 'None (1)'	System	06 Sep 2020 04:15:32

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:28', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b6c739a7-e4e1-4dd2-93ba-005f4aeada5a'	System	06 Sep 2020 04:15:32
User entered '05 Sep 2020 21:15'	System	06 Sep 2020 04:15:32

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 7'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b4cc8282-85f8-4d64-ad01-cb52dddc777'	System	07 Sep 2020 01:00:12
User entered 'None (1)'	System	07 Sep 2020 01:00:12

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b4cc8282-85f8-4d64-ad01-cb52dddc777'	System	07 Sep 2020 01:00:12
User entered 'No (N)'	System	07 Sep 2020 01:00:12

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T17:59:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b4cc8282-85f8-4d64-ad01-cb52dddc777'	System	07 Sep 2020 01:00:12
User entered 'No (N)'	System	07 Sep 2020 01:00:12

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b4cc8282-85f8-4d64-ad01-cb52dddc777'	System	07 Sep 2020 01:00:12
User entered 'None (1)'	System	07 Sep 2020 01:00:12

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b4cc8282-85f8-4d64-ad01-cb52dddc777'	System	07 Sep 2020 01:00:12
User entered '06 Sep 2020 18:00'	System	07 Sep 2020 01:00:12

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:53', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:23:57', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:05', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:06', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'None (0)'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered 'No (N)'	System	01 Sep 2020 01:24:15



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T18:24:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '739c2a07-27f7-4ccb-a12e-9a196b4216b2'	System	01 Sep 2020 01:24:15
User entered '31 Aug 2020 18:24'	System	01 Sep 2020 01:24:15

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 18:11'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 20:41'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:06', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'None (0)'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered 'No (N)'	System	01 Sep 2020 05:16:23

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-08-31T22:16:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '844d7644-1d5d-4110-813c-6d6b06bf6351'	System	01 Sep 2020 05:16:23
User entered '31 Aug 2020 22:16'	System	01 Sep 2020 05:16:23

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '31 Aug 2020 21:36'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 2'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:11:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'None (0)'	System	01 Sep 2020 23:13:50



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:13:36', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'Some interference with activity (2)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:12:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'Some interference with activity (2)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:12:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'Some interference with activity (2)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:13:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'None (0)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:13:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'None (0)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:13:09', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered 'No (N)'	System	01 Sep 2020 23:13:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-01T16:13:48', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e090bcac-f776-4359-8c3a-04eb90da3880'	System	01 Sep 2020 23:13:50
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 23:13:50

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 00:57:27



**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 3'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:36', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:43', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:48', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:52', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:28:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'None (0)'	System	03 Sep 2020 04:29:10



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:29:02', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered 'No (N)'	System	03 Sep 2020 04:29:10

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-02T21:29:05', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'bdb2807f-5803-41d4-905d-18197135dd90'	System	03 Sep 2020 04:29:10
User entered '02 Sep 2020 21:29'	System	03 Sep 2020 04:29:10

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:08:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 4'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:32', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered 'None (0)'	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered 'None (0)'	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804' User entered 'None (0)'	System	04 Sep 2020 05:37:54
	System	04 Sep 2020 05:37:54



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:42', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804' User entered 'None (0)'	System	04 Sep 2020 05:37:54
	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered 'None (0)'	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered 'None (0)'	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:50', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered 'No (N)'	System	04 Sep 2020 05:37:54

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-03T22:37:52', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0aa6b93-1d62-47fe-b5f2-6fb21ba9b804'	System	04 Sep 2020 05:37:54
User entered '03 Sep 2020 22:37'	System	04 Sep 2020 05:37:54

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 5'	System	01 Sep 2020 00:57:27



**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'No interference with activity (1)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'None (0)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:15', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'None (0)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:18', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'None (0)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'None (0)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'None (0)'	System	05 Sep 2020 03:41:36

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:26', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered 'No (N)'	System	05 Sep 2020 03:41:36

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-04T20:41:32', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '919e38ef-4f07-4b02-a520-8158ca5abfba'	System	05 Sep 2020 03:41:36
User entered '04 Sep 2020 20:41'	System	05 Sep 2020 03:41:36



**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 6'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:33', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:39', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50



**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:40', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'None (0)'	System	06 Sep 2020 04:15:50

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered 'No (N)'	System	06 Sep 2020 04:15:50

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-05T21:15:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '50166fbb-b5a9-4d37-a4bc-83307da069f2'	System	06 Sep 2020 04:15:50
User entered '05 Sep 2020 21:15'	System	06 Sep 2020 04:15:50

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 00:57:27

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	01 Sep 2020 00:57:27
User entered 'Day 7'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:11', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31



US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:15', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:22', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'None (0)'	System	07 Sep 2020 01:00:31

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

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)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:24', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered 'No (N)'	System	07 Sep 2020 01:00:31

US3112071

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:08:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-09-06T18:00:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '54106174-350f-4c7b-907c-cdd287ba2399'	System	07 Sep 2020 01:00:31
User entered '06 Sep 2020 18:00'	System	07 Sep 2020 01:00:31

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 00:57:27

**US3112071**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:08:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 00:57:27



**US3112071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'No (N)'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:02

**US3112071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:02

**US3112071**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:02

US3112071

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered empty.	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:02

US3112071

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:33:33
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:11

**US3112071**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	15 Sep 2020 00:29:11

**US3112071**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:26

US3112071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '14 Sep 2020'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:26



US3112071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:26

US3112071

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:26

US3112071

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	15 Sep 2020 00:29:34

**US3112071**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	15 Sep 2020 00:29:34

**US3112071**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	21 Sep 2020 18:19:39

US3112071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '21 Sep 2020'	Karen Mylerberg (b) (4)	21 Sep 2020 18:19:39

US3112071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	21 Sep 2020 18:19:39

US3112071

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Karen Mylerberg (b) (4)	21 Sep 2020 18:19:39



US3112071

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	21 Sep 2020 18:19:47

**US3112071**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	21 Sep 2020 18:19:47

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 20:12:04

US3112071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '29 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 20:12:04

US3112071

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	08 Oct 2020 20:12:04

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'VISIT3'	System	08 Oct 2020 20:12:04

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '29 Sep 2020'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17



**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:16'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '29 Sep 2020 16:16'	System	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '98.8' F	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '62'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'bpm'	System	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17



US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'breaths/min'	System	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '107'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	08 Oct 2020 20:13:17

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '62'	Natalie Moy (b) (4)	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'mmHg'	System	08 Oct 2020 20:13:17

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53

US3112071

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53

US3112071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'No (N)'	Natalie Moy (b) (4)	08 Oct 2020 20:13:24



US3112071

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered empty.	Natalie Moy (b) (4)	08 Oct 2020 20:13:24

US3112071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 20:13:40

US3112071

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 30sep2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 08:20:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 30sep2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you ' answered with 'The correct date is 29Sep2020' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	03 Nov 2020 18:04:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 29sep2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 3 Day 57 Visit with date 30sep2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:32:45
User entered '29 Sep 2020'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 20:13:40

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered '16:40'	Natalie Moy (b) (4)	08 Oct 2020 20:13:40

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered '29 Sep 2020 16:40'	System	08 Oct 2020 20:13:40

US3112071

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:41:48
User entered 'Yes (Y)'	Natalie Moy (b) (4)	08 Oct 2020 20:13:52

**US3112071**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	08 Oct 2020 20:13:52

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 64'	System	04 Aug 2020 00:40:43



US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-03T08:59:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'dad2c903-dcd8-4eae-be78-abcfa66189f'	System	03 Oct 2020 15:59:49
User entered 'No (N)'	System	03 Oct 2020 15:59:49

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-03T08:58:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'dad2c903-dcd8-4eae-be78-abcfa66189f'	System	03 Oct 2020 15:59:49
User entered 'No (N)'	System	03 Oct 2020 15:59:49

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-03T08:59:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'dad2c903-dcd8-4eae-be78-abcfa66189f' User entered '03 Oct 2020 08:59:44'	System	03 Oct 2020 15:59:49
	System	03 Oct 2020 15:59:49

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '03 Oct 2020 00:01'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '07 Oct 2020 23:59'	System	04 Aug 2020 00:40:43

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 71'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-10T10:37:42', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd328b061-14f7-4ad3-a5e8-3ddf1e306d97'	System	10 Oct 2020 15:37:59
User entered 'No (N)'	System	10 Oct 2020 15:37:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-10T10:37:50', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd328b061-14f7-4ad3-a5e8-3ddf1e306d97'	System	10 Oct 2020 15:37:59
User entered 'No (N)'	System	10 Oct 2020 15:37:59



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-10T10:37:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd328b061-14f7-4ad3-a5e8-3ddf1e306d97'	System	10 Oct 2020 15:37:59
User entered '10 Oct 2020 10:37:55'	System	10 Oct 2020 15:37:59

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '10 Oct 2020 00:01'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '14 Oct 2020 23:59'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 78'	System	04 Aug 2020 00:40:43

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-17T09:16:20', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a3eaa863-2f82-45aa-be44-5250ecc162dd'	System	17 Oct 2020 16:16:32
User entered 'No (N)'	System	17 Oct 2020 16:16:32

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-17T09:16:24', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a3eaa863-2f82-45aa-be44-5250ecc162dd'	System	17 Oct 2020 16:16:32
User entered 'No (N)'	System	17 Oct 2020 16:16:32

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-10-17T09:16:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a3eaa863-2f82-45aa-be44-5250ecc162dd'	System	17 Oct 2020 16:16:32
User entered '17 Oct 2020 09:16:27'	System	17 Oct 2020 16:16:32

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '17 Oct 2020 00:01'	System	04 Aug 2020 00:40:43



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '21 Oct 2020 23:59'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 92'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '31 Oct 2020 00:01'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:14:10
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '04 Nov 2020 23:59'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 99'	System	04 Aug 2020 00:40:43

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-07T09:01:29', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd49b6159-58b0-4bec-bd6a-5cf1ecc80007'	System	07 Nov 2020 17:01:59
User entered 'No (N)'	System	07 Nov 2020 17:01:59

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-07T09:01:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd49b6159-58b0-4bec-bd6a-5cf1ecc80007'	System	07 Nov 2020 17:01:59
User entered 'No (N)'	System	07 Nov 2020 17:01:59



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-07T09:01:44', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd49b6159-58b0-4bec-bd6a-5cf1ecc80007' User entered '07 Nov 2020 09:01:44'	System	07 Nov 2020 17:01:59
	System	07 Nov 2020 17:01:59

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '07 Nov 2020 00:01'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '11 Nov 2020 23:59'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered 'Day 106'	System	04 Aug 2020 00:40:43

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-17T13:38:51', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '34cbf03e-ffd6-4baa-a6a2-29db71785ca2'	System	17 Nov 2020 21:39:35
User entered 'No (N)'	System	17 Nov 2020 21:39:35

US3112071

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-17T13:38:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '34cbf03e-ffd6-4baa-a6a2-29db71785ca2'	System	17 Nov 2020 21:39:35
User entered 'Yes (Y)'	System	17 Nov 2020 21:39:35

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-17T13:39:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '34cbf03e-ffd6-4baa-a6a2-29db71785ca2'	System	17 Nov 2020 21:39:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 21:39:35

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-17T13:39:24', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '34cbf03e-ffd6-4baa-a6a2-29db71785ca2'	System	17 Nov 2020 21:39:35
User entered '17 Nov 2020 13:39:24'	System	17 Nov 2020 21:39:35



**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '14 Nov 2020 00:01'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:09:21
Data entry locked.	System	04 Aug 2020 00:40:43
User entered '18 Nov 2020 23:59'	System	04 Aug 2020 00:40:43

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-11-21T09:23:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '327b2fb7-9c44-43ec-baa0-6725e8ba55bc'	System	21 Nov 2020 17:23:20
User entered 'No (N)'	System	21 Nov 2020 17:23:20

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-11-21T09:23:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '327b2fb7-9c44-43ec-baa0-6725e8ba55bc'	System	21 Nov 2020 17:23:20
User entered 'No (N)'	System	21 Nov 2020 17:23:20

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-21T09:23:14', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '327b2fb7-9c44-43ec-baa0-6725e8ba55bc'	System	21 Nov 2020 17:23:20
User entered '21 Nov 2020 09:23:14'	System	21 Nov 2020 17:23:20

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-11-25T07:49:15', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5426ecd8-2b80-48f7-be37-c127f1afa64f'	System	25 Nov 2020 15:49:32
User entered 'No (N)'	System	25 Nov 2020 15:49:32

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-11-25T07:49:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5426ecd8-2b80-48f7-be37-c127f1afa64f'	System	25 Nov 2020 15:49:32
User entered 'No (N)'	System	25 Nov 2020 15:49:32

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-11-25T07:49:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '5426ecd8-2b80-48f7-be37-c127f1afa64f' User entered '25 Nov 2020 07:49:27'	System	25 Nov 2020 15:49:32
	System	25 Nov 2020 15:49:32

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-12-02T08:01:13', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0513b62-8b28-4f07-becc-0adefed058ea'	System	02 Dec 2020 16:01:27
User entered 'No (N)'	System	02 Dec 2020 16:01:27



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-12-02T08:01:17', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0513b62-8b28-4f07-becc-0adefed058ea'	System	02 Dec 2020 16:01:27
User entered 'No (N)'	System	02 Dec 2020 16:01:27

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-12-02T08:01:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b0513b62-8b28-4f07-becc-0adefed058ea' User entered '02 Dec 2020 08:01:23'	System	02 Dec 2020 16:01:27
	System	02 Dec 2020 16:01:27

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-12-09T08:30:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ef8bd42b-6521-42be-abf5-406eb864e056'	System	09 Dec 2020 16:30:14
User entered 'No (N)'	System	09 Dec 2020 16:30:14

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-12-09T08:30:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ef8bd42b-6521-42be-abf5-406eb864e056'	System	09 Dec 2020 16:30:14
User entered 'No (N)'	System	09 Dec 2020 16:30:14

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-12-09T08:30:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'ef8bd42b-6521-42be-abf5-406eb864e056'	System	09 Dec 2020 16:30:14
User entered '09 Dec 2020 08:30:10'	System	09 Dec 2020 16:30:14



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-12-16T08:05:18', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'adea28f3-9677-47f6-97a1-870614feb37f'	System	16 Dec 2020 16:05:33
User entered 'No (N)'	System	16 Dec 2020 16:05:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-12-16T08:05:21', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'adea28f3-9677-47f6-97a1-870614feb37f'	System	16 Dec 2020 16:05:33
User entered 'No (N)'	System	16 Dec 2020 16:05:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-12-16T08:05:25', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'adea28f3-9677-47f6-97a1-870614feb37f'	System	16 Dec 2020 16:05:33
User entered '16 Dec 2020 08:05:25'	System	16 Dec 2020 16:05:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-12-25T14:15:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9d67d5c0-afdb-4040-aff1-0af883b314bb'	System	25 Dec 2020 22:15:45
User entered 'No (N)'	System	25 Dec 2020 22:15:45

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-12-25T14:15:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9d67d5c0-afdb-4040-aff1-0af883b314bb'	System	25 Dec 2020 22:15:45
User entered 'No (N)'	System	25 Dec 2020 22:15:45

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-12-25T14:15:41', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9d67d5c0-afdb-4040-aff1-0af883b314bb' User entered '25 Dec 2020 14:15:41'	System	25 Dec 2020 22:15:45
	System	25 Dec 2020 22:15:45

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2020-12-30T08:09:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd04f8892-ddba-48c9-82d1-5661ab9fc698'	System	30 Dec 2020 16:09:41
User entered 'No (N)'	System	30 Dec 2020 16:09:41



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2020-12-30T08:09:30', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd04f8892-ddba-48c9-82d1-5661ab9fc698'	System	30 Dec 2020 16:09:41
User entered 'No (N)'	System	30 Dec 2020 16:09:41

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2020-12-30T08:09:38', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'd04f8892-ddba-48c9-82d1-5661ab9fc698'	System	30 Dec 2020 16:09:41
User entered '30 Dec 2020 08:09:38'	System	30 Dec 2020 16:09:41

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-06T08:04:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fbf086ae-5b6b-4db3-aa7f-cd76c540ae4a'	System	06 Jan 2021 16:04:41
User entered 'No (N)'	System	06 Jan 2021 16:04:41

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-01-06T08:04:33', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fbf086ae-5b6b-4db3-aa7f-cd76c540ae4a'	System	06 Jan 2021 16:04:41
User entered 'No (N)'	System	06 Jan 2021 16:04:41

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-01-06T08:04:37', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'fbf086ae-5b6b-4db3-aa7f-cd76c540ae4a'	System	06 Jan 2021 16:04:41
User entered '06 Jan 2021 08:04:37'	System	06 Jan 2021 16:04:41



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-13T08:54:28', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7bb4d3bb-512c-4051-9eb0-e8f7a857fc17'	System	13 Jan 2021 16:54:37
User entered 'No (N)'	System	13 Jan 2021 16:54:37

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-01-13T08:54:31', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7bb4d3bb-512c-4051-9eb0-e8f7a857fc17'	System	13 Jan 2021 16:54:37
User entered 'No (N)'	System	13 Jan 2021 16:54:37

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-01-13T08:54:35', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '7bb4d3bb-512c-4051-9eb0-e8f7a857fc17'	System	13 Jan 2021 16:54:37
User entered '13 Jan 2021 08:54:35'	System	13 Jan 2021 16:54:37

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-21T19:56:52', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d'	System	22 Jan 2021 02:57:25
User entered 'Yes (Y)'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-01-21T19:56:55', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d'	System	22 Jan 2021 02:57:25
User entered 'No (N)'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-21T19:57:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d'	System	22 Jan 2021 02:57:25
User entered 'No (N)'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-21T19:57:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d'	System	22 Jan 2021 02:57:25
User entered 'Yes (Y)'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Please 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 (f32b0777e193bd54)', Time: '2021-01-21T19:57:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d'	System	22 Jan 2021 02:57:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-01-21T19:57:14', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '02908e1c-c3ae-4f39-8d45-c89f8918d51d' User entered '21 Jan 2021 19:57:14'	System	22 Jan 2021 02:57:25

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-01-27T08:09:04', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a13a181f-89e1-44e3-9b5a-23dbd109b8f9'	System	27 Jan 2021 16:09:14
User entered 'No (N)'	System	27 Jan 2021 16:09:14

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-01-27T08:09:08', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a13a181f-89e1-44e3-9b5a-23dbd109b8f9'	System	27 Jan 2021 16:09:14
User entered 'No (N)'	System	27 Jan 2021 16:09:14

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-01-27T08:09:12', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'a13a181f-89e1-44e3-9b5a-23dbd109b8f9'	System	27 Jan 2021 16:09:14
User entered '27 Jan 2021 08:09:12'	System	27 Jan 2021 16:09:14

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

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 (f32b0777e193bd54)', Time: '2021-02-03T08:22:46', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1ff81993-9129-4caf-864a-805611f04d25'	System	03 Feb 2021 16:23:06
User entered 'No (N)'	System	03 Feb 2021 16:23:06

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-02-03T08:22:58', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1ff81993-9129-4caf-864a-805611f04d25'	System	03 Feb 2021 16:23:06
User entered 'No (N)'	System	03 Feb 2021 16:23:06

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-02-03T08:23:02', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '1ff81993-9129-4caf-864a-805611f04d25'	System	03 Feb 2021 16:23:06
User entered '03 Feb 2021 08:23:02'	System	03 Feb 2021 16:23:06

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-02-10T07:32:03', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e7589777-3e2a-4edb-99fc-035289a1bffd'	System	10 Feb 2021 15:32:15
User entered 'No (N)'	System	10 Feb 2021 15:32:15

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-02-10T07:32:07', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e7589777-3e2a-4edb-99fc-035289a1bffd'	System	10 Feb 2021 15:32:15
User entered 'No (N)'	System	10 Feb 2021 15:32:15



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-02-10T07:32:10', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e7589777-3e2a-4edb-99fc-035289a1bffd'	System	10 Feb 2021 15:32:15
User entered '10 Feb 2021 07:32:10'	System	10 Feb 2021 15:32:15

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-02-19T20:41:02', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '799682e4-2f90-468a-a15c-d447d386e01b'	System	20 Feb 2021 04:41:30
User entered 'No (N)'	System	20 Feb 2021 04:41:30

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-02-19T20:41:23', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '799682e4-2f90-468a-a15c-d447d386e01b'	System	20 Feb 2021 04:41:30
User entered 'No (N)'	System	20 Feb 2021 04:41:30

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-02-19T20:41:27', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '799682e4-2f90-468a-a15c-d447d386e01b'	System	20 Feb 2021 04:41:30
User entered '19 Feb 2021 20:41:27'	System	20 Feb 2021 04:41:30

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-02-24T08:35:51-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9cc86367-0752-408f-99c0-382aef56a686'	System	24 Feb 2021 16:36:02
User entered 'No (N)'	System	24 Feb 2021 16:36:02

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-02-24T08:35:55-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9cc86367-0752-408f-99c0-382aef56a686'	System	24 Feb 2021 16:36:02
User entered 'No (N)'	System	24 Feb 2021 16:36:02

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-02-24T08:35:58-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '9cc86367-0752-408f-99c0-382aef56a686'	System	24 Feb 2021 16:36:02
User entered '24 Feb 2021 08:35:58'	System	24 Feb 2021 16:36:02

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-03-03T08:02:27-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e64fb91a-f900-4a11-adaf-d66885b90b43'	System	03 Mar 2021 16:02:39
User entered 'No (N)'	System	03 Mar 2021 16:02:39

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-03-03T08:02:32-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e64fb91a-f900-4a11-adaf-d66885b90b43'	System	03 Mar 2021 16:02:39
User entered 'No (N)'	System	03 Mar 2021 16:02:39

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-03-03T08:02:35-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'e64fb91a-f900-4a11-adaf-d66885b90b43'	System	03 Mar 2021 16:02:39
User entered '03 Mar 2021 08:02:35'	System	03 Mar 2021 16:02:39

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-03-10T08:55:24-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3b30f50-710d-4757-94f5-87ffe8cc0fa4'	System	10 Mar 2021 16:55:54
User entered 'No (N)'	System	10 Mar 2021 16:55:54

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-03-10T08:55:31-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3b30f50-710d-4757-94f5-87ffe8cc0fa4'	System	10 Mar 2021 16:55:54
User entered 'No (N)'	System	10 Mar 2021 16:55:54



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-03-10T08:55:35-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'f3b30f50-710d-4757-94f5-87ffe8cc0fa4'	System	10 Mar 2021 16:55:54
User entered '10 Mar 2021 08:55:35'	System	10 Mar 2021 16:55:54

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-03-24T22:03:53-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8e6f2606-1d26-4572-bb17-8c0310f393eb'	System	25 Mar 2021 05:04:05
User entered 'No (N)'	System	25 Mar 2021 05:04:05



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-03-24T22:03:57-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8e6f2606-1d26-4572-bb17-8c0310f393eb'	System	25 Mar 2021 05:04:05
User entered 'No (N)'	System	25 Mar 2021 05:04:05

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-03-24T22:04:01-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '8e6f2606-1d26-4572-bb17-8c0310f393eb' User entered '24 Mar 2021 22:04:01'	System	25 Mar 2021 05:04:05
	System	25 Mar 2021 05:04:05

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-04-02T10:32:43-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4cadf3c9-7c40-461a-9388-bedd319d80cc' User entered 'No (N)'	System	02 Apr 2021 17:32:54
	System	02 Apr 2021 17:32:54

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-04-02T10:32:46-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4cadf3c9-7c40-461a-9388-bedd319d80cc'	System	02 Apr 2021 17:32:54
User entered 'No (N)'	System	02 Apr 2021 17:32:54

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-04-02T10:32:50-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '4cadf3c9-7c40-461a-9388-bedd319d80cc'	System	02 Apr 2021 17:32:54
User entered '02 Apr 2021 10:32:50'	System	02 Apr 2021 17:32:54



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-04-11T20:15:03-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3642ef48-2eb2-4ea5-9224-d95c474f5435'	System	12 Apr 2021 03:15:23
User entered 'No (N)'	System	12 Apr 2021 03:15:23

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-04-11T20:15:15-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3642ef48-2eb2-4ea5-9224-d95c474f5435'	System	12 Apr 2021 03:15:23
User entered 'No (N)'	System	12 Apr 2021 03:15:23

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-04-11T20:15:18-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '3642ef48-2eb2-4ea5-9224-d95c474f5435'	System	12 Apr 2021 03:15:23
User entered '11 Apr 2021 20:15:18'	System	12 Apr 2021 03:15:23

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-04-21T19:02:06-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '52ab05a8-05fd-45ac-b3ef-7137ad9c71b5' User entered 'No (N)'	System	22 Apr 2021 02:04:33
	System	22 Apr 2021 02:04:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-04-21T19:02:09-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '52ab05a8-05fd-45ac-b3ef-7137ad9c71b5'	System	22 Apr 2021 02:04:33
User entered 'No (N)'	System	22 Apr 2021 02:04:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-04-21T19:02:12-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: '52ab05a8-05fd-45ac-b3ef-7137ad9c71b5'	System	22 Apr 2021 02:04:33
User entered '21 Apr 2021 19:02:12'	System	22 Apr 2021 02:04:33

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[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 (f32b0777e193bd54)', Time: '2021-05-02T21:26:31-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b243bcf2-06f1-418f-a921-615bb4d5aafe'	System	03 May 2021 04:26:47
User entered 'No (N)'	System	03 May 2021 04:26:47

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

Have you been exposed to someone with 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 (f32b0777e193bd54)', Time: '2021-05-02T21:26:39-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b243bcf2-06f1-418f-a921-615bb4d5aafe'	System	03 May 2021 04:26:47
User entered 'No (N)'	System	03 May 2021 04:26:47

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-05-02T21:26:42-07:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'b243bcf2-06f1-418f-a921-615bb4d5aafe'	System	03 May 2021 04:26:47
User entered '02 May 2021 21:26:42'	System	03 May 2021 04:26:47

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:14:10



**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:14:10

**US3112071**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:08:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:14:10
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:14:10



US3112071

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:08:25**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-03-03T08:02:52-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'c4792fd0-a7f8-4dd6-8582-a2f857fd1895'	System	03 Mar 2021 16:02:59
User entered 'No (N)'	System	03 Mar 2021 16:02:59

**US3112071**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:05:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f32b0777e193bd54)', Time: '2021-03-03T08:02:56-08:00', User OID: 'PatientReportedOutcome (US3112071)', ODM File OID: 'c4792fd0-a7f8-4dd6-8582-a2f857fd1895'	System	03 Mar 2021 16:02:59
User entered '03 Mar 2021 08:02:56'	System	03 Mar 2021 16:02:59

**US3112071**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:42:17
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Oct 2020 23:18:59

**US3112071**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:42:17
User entered '26 Oct 2020'	Natalie Moy (b) (4)	26 Oct 2020 23:18:59

US3112071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:42:17
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	26 Oct 2020 23:18:59

US3112071

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:42:17
User entered empty.	Natalie Moy (b) (4)	26 Oct 2020 23:18:59

US3112071

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:42:17
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Oct 2020 23:19:03

**US3112071**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:42:53
User entered 'I'	System	26 Oct 2020 23:19:03



**US3112071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	30 Nov 2020 20:23:16

**US3112071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '30 Nov 2020'	Natalie Moy (b) (4)	30 Nov 2020 20:23:16

**US3112071**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	30 Nov 2020 20:23:16

US3112071

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	30 Nov 2020 20:23:16

US3112071

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	30 Nov 2020 20:23:27

**US3112071**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'I'	System	30 Nov 2020 20:23:27

**US3112071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	28 Dec 2020 21:40:14

**US3112071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '28 Dec 2020'	Brenda Grande (b) (4)	28 Dec 2020 21:40:14



**US3112071**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	28 Dec 2020 21:40:14

US3112071

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Brenda Grande (b) (4)	28 Dec 2020 21:40:14

US3112071

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	28 Dec 2020 21:40:19

**US3112071**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'I'	System	28 Dec 2020 21:40:19

**US3112071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	23 Feb 2021 20:00:03

**US3112071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '27 Jan 2021'	Brenda Grande (b) (4)	23 Feb 2021 20:00:03

**US3112071**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	23 Feb 2021 20:00:03

US3112071

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Brenda Grande (b) (4)	23 Feb 2021 20:00:03



US3112071

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	23 Feb 2021 19:59:48

**US3112071**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'I'	System	23 Feb 2021 19:59:48

US3112071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:51

US3112071

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Mar 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:56:51

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:51

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'VISIT4'	System	02 Mar 2021 21:56:51

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Mar 2021'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01



US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '16:23'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered '1 Mar 2021 16:23'	System	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '98.8' F	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '67'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'bpm'	System	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '16'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01



US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'breaths/min'	System	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '138'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'mmHg'	System	29 Mar 2021 23:12:01

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '82'	Brenda Grande (b) (4)	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'mmHg'	System	29 Mar 2021 23:12:01

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:08:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57

US3112071

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:08:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57

US3112071

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:08:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:57



**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:08:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:56:57

US3112071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Mar 2021 21:57:10

US3112071

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Mar 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:57:10

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '16:40'	Natalie Moy (b) (4)	02 Mar 2021 21:57:10

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered '1 Mar 2021 16:40'	System	02 Mar 2021 21:57:10

US3112071

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Mar 2021 21:57:41

**US3112071**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:44:57
User entered 'I'	System	02 Mar 2021 21:57:41

**US3112071**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:08:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 23:11:23



US3112071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '29 Mar 2021'	Brenda Grande (b) (4)	29 Mar 2021 23:11:23

US3112071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	29 Mar 2021 23:11:23

US3112071

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:08:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Brenda Grande (b) (4)	29 Mar 2021 23:11:23

US3112071

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:08:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 23:11:25

**US3112071**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:39:41
User entered 'I'	System	29 Mar 2021 23:11:25

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Feb 2021 00:35:48

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Feb 2021'	Natalie Moy (b) (4)	02 Feb 2021 00:35:48

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:08:25

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	02 Feb 2021 00:35:48



**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:08:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 00:35:48

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:08:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Feb 2021'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:46:56
User entered '0'	Brenda Grande (b) (4)	08 Apr 2021 17:02:30
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:18:58

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:08:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:01:18
User signature succeeded.	Todd Simmons (b) (4)	08 Apr 2021 22:46:56
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	08 Apr 2021 17:02:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4)	08 Apr 2021 17:02:30
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:18:37
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:18:58

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:08:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1 Feb 2021'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04



**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:08:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:04

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User entered empty.	System	02 Feb 2021 00:36:04

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:08:25**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User entered empty.	System	02 Feb 2021 00:36:04

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:14

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-Query: Per response is noted. However, please confirm the correct date (01FEB2021 or 02FEB2021) for this OL-D1 visit in the query response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:10:21
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-Query: Per response is noted. However, please confirm the correct date (01FEB2021 or 02FEB2021) for this OL-D1 visit in the query response. Thank you.' answered with 'correct date is 01FEB2021' (Site from DM).	Brenda Grande (b) (4)	24 Feb 2021 22:13:05
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-Query: Per response is noted. However, please confirm the correct date (01FEB2021 or 02FEB2021) for this OL-D1 visit in the query response. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:36:40
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 02FEB2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 01FEB2021. Please confirm the correct Collection Date in the query response box and update EDC if necessary. Please be sure to reconcile the PPD portal, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:36:40
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 02FEB2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 01FEB2021. Please confirm the correct Collection Date in the query response box and update EDC if necessary. Please be sure to reconcile the PPD portal, as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	11 Feb 2021 22:32:47

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 02FEB2021 for the Participant Decision Visit / OL-D1, however, the Collection Date recorded here is 01FEB2021. Please confirm the correct Collection Date in the query response box and update EDC if necessary. Please be sure to reconcile the PPD portal, as appropriate. ' (Site from DM). User entered '1 Feb 2021'	(b) (4), (b) (6) (b) (4)	11 Feb 2021 15:34:23
	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 00:36:14

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '15:15'	Natalie Moy (b) (4)	02 Feb 2021 00:36:14



**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:08:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User entered '1 Feb 2021 15:15'	System	02 Feb 2021 00:36:14

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Feb 2021 00:36:21

US3112071

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01FEB2021 under Participant Decision Visit/OL-D1 Day 1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:28:53
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01FEB2021 under Participant Decision Visit/OL-D1 Day 1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'sample was collected on 1FEB2021 and has been shipped ' (Site from DM).	Brenda Grande (b) (4)	15 Feb 2021 17:11:54
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01FEB2021 under Participant Decision Visit/OL-D1 Day 1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:36:48
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 02FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is reported as 01FEB2021 in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:36:40
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 02FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is reported as 01FEB2021 in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 05:37:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:08:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '1 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 00:36:21

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:08:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '14:41'	Natalie Moy (b) (4)	02 Feb 2021 00:36:21

**US3112071**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:08:25**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:15:43
User entered '1 Feb 2021 14:41'	System	02 Feb 2021 00:36:21

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:08:25**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:43:29
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:09
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Pyelonephritis, LLT: Pyelonephritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:56:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:56:06
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 20:54:52
User entered 'Pyelonephritis'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '18 Jan 2021'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 20:54:21

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 20:54:21

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'None (NONE)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:08:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'I'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered '0'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered 'Unknown (UNKNOWN)'	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:35:22
User entered empty.	Matthew Musikanth	22 Jan 2021 20:54:21
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 20:54:21



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Jan 2021 20:54:21

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:51
User entered	System	25 Jan 2021 16:52:46
'USA-US062-2021-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 16:52:46

US3112071

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:57:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 20:57:05
Data point term sent to Coder	System	22 Jan 2021 20:55:52
User entered 'Sepsis'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'No (N)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '18 Jan 2021'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered empty.	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 20:55:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:10:52
DataPoint Un-verified.	Matthew Musikanth	01 Feb 2021 19:55:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth	01 Feb 2021 19:55:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:10:54
DataPoint Un-verified.	Matthew Musikanth	01 Feb 2021 19:55:30
	(b) (4)	
User entered '31 Jan 2021' reason for change: Data Entry Error	Matthew Musikanth	01 Feb 2021 19:55:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered empty.	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered empty.	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:50:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:40:12
User entered empty.	System	22 Jan 2021 20:55:37

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		22 Jan 2021 20:55:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		22 Jan 2021 20:55:56
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Jan 2021 20:55:37
User entered 'I'	Matthew Musikanth (b) (4)	22 Jan 2021 20:55:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '18 Jan 2021'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '21 Jan 2021'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:13:35
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Feb 2021 19:55:30
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		01 Feb 2021 19:55:30
DataPoint Un-verified.	Matthew Musikanth (b) (4)	01 Feb 2021 19:55:30
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Feb 2021 19:55:30
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Jan 2021 20:55:56
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Jan 2021 20:55:56
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 20:55:37

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered empty.	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	



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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'I'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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**Folder: Adverse Events**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered '0'	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:11:03
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:29
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	01 Feb 2021 19:55:36
DataPoint Un-verified.	Matthew Musikanth (b) (4)	01 Feb 2021 19:55:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Feb 2021 19:55:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:40:57
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered 'Unknown (UNKNOWN)'	Matthew Musikanth (b) (4)	22 Jan 2021 20:55:37



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:36:21
User entered empty.	Matthew Musikanth	22 Jan 2021 20:55:37
	(b) (4)	

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Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:44
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. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:40
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 15:32:35
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)	02 Feb 2021 15:32:32
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. ' answered with 'sent' (Site from Safety).	Matthew Musikanth (b) (4)	01 Feb 2021 22:06:48

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:08:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Sent' (Site from Safety).	Matthew Musikanth (b) (4)	01 Feb 2021 22:06:44
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 'COVID-19 NAA Screening, Collected 18Jan2021, NEGATIVE' (Site from Safety).	Matthew Musikanth (b) (4)	01 Feb 2021 19:59:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Medications added. ' (Site from Safety).	Matthew Musikanth (b) (4)	01 Feb 2021 19:56:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:41:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:40:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 19:39:42

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 19:38:43
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Jan 2021 20:58:16
User entered 'pt presented at hospital for pain while urinating, ad. pain, and fever. Was admitted to treat for pyelonephritis and sepsis.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Jan 2021 20:58:16
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 20:55:37
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 20:55:37

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 20:55:37

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 20:55:37

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 20:55:56

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:08:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Atmospheric pressure injuries, PT: Hypobarism, LLT: Altitude sickness - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 18:48:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 18:48:30
Data point term sent to Coder	System	01 Feb 2021 18:47:12
User entered 'Altitude Sickness'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

US3112071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '22 Jan 2021'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User entered empty.	System	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '22 Jan 2021'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User entered empty.	System	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

US3112071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:08:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11



US3112071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:08:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

US3112071

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:08:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'I'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:47:11



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User entered '0'	System	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11
User entered 'I'	System	01 Feb 2021 18:47:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:11

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User coded data point as SOC: Reproductive system and breast disorders, HLG: Male reproductive tract infections and inflammations, HLT: Prostate and seminal vesicles infections and inflammations, PT: Prostatitis, LLT: Prostatitis - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 21:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 21:55:48
Data point term sent to Coder	System	02 Mar 2021 21:55:34
User entered 'prostatitis'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Yes (Y)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '04 Feb 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User entered empty.	System	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '22 Feb 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User entered empty.	System	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

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**Generated On: 09 Jun 2021 15:08:25**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

US3112071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

US3112071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06



**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'None (NONE)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

US3112071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'I'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06



US3112071

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:08:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:18:11
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User entered '0'	System	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15
User entered 'I'	System	02 Mar 2021 21:55:06

**US3112071**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:32:15

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:08:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:43:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:38:11
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:52:07



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 17:57:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 17:57:01
Data point term sent to Coder	System	04 Aug 2020 17:55:19
User entered 'Flomax'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Benign Prostatic Hyperplasia'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0.4'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mg (mg)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'once daily (QD)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 12:27:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 17:54:34
User entered 'un UNK 2015'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:54:34
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:54:34



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:54:34

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 17:54:34

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:23:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:23:20
Data point term sent to Coder	System	04 Aug 2020 17:56:20
User entered 'Testosterone'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Health supplement'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '1'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'capsule (CAPSULE)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'once daily (QD)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '15 Jul 2020'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:08:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	



US3112071

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Karen Mylerberg (b) (4)	04 Aug 2020 17:55:46
	(b) (4)	

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:55:46

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:55:46

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 17:55:46

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:49:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 03:49:44
Data point term sent to Coder Coding entries removed.	System Karen Mylerberg (b) (4)	14 Sep 2020 00:34:15 14 Sep 2020 00:33:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 23:30:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 23:30:22
Data point term sent to Coder User entered 'Ibuprofen'	System Laurie Han-Conrad (b) (4)	10 Aug 2020 17:12:03 10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User closed query 'Per DM CLR: Please update the indication to reflect the location of ANKLE PAIN (left, right or bilateral). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:46:24
Query 'Per DM CLR: Please update the indication to reflect the location of ANKLE PAIN (left, right or bilateral). Please reconcile with Med History eCRF as appropriate. ' answered with 'Med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	14 Sep 2020 00:33:55
User entered 'ANKLE PAIN-bilateral' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	14 Sep 2020 00:33:40
User opened query 'Per DM CLR: Please update the indication to reflect the location of ANKLE PAIN (left, right or bilateral). Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 08:34:55
User entered 'Ankle pain'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '400'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mg (mg)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'as needed (PRN)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Oral (ORAL)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '01 Aug 2020' reason for change: Data Entry Error	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:32:58
User entered '05 Aug 2020'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '09 Aug 2020'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User entered empty.	System	10 Aug 2020 17:11:29

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User entered empty.	System	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:08:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:06
User entered empty.	System	10 Aug 2020 17:11:29

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 23:22:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 23:22:25
Data point term sent to Coder	System	26 Oct 2020 23:21:27
User entered 'flu vaccine'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Yes (Y)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'influenza virus prophylaxis'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0.5'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mL (mL)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'once (ONCE)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:08:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	26 Oct 2020 23:21:04



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '5 Oct 2020'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '5 Oct 2020'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User entered empty.	System	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User entered empty.	System	26 Oct 2020 23:21:04

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:10
User entered empty.	System	26 Oct 2020 23:21:04



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 07:58:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 07:58:45
Data point term sent to Coder	System	01 Feb 2021 18:46:09
User entered 'Ceftriaxone'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'Sepsis'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered '2'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'g (g)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered '18 Jan 2021'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered '18 Jan 2021'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:08:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:37:15
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:45:16

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User entered empty.	System	01 Feb 2021 18:45:16



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User entered empty.	System	01 Feb 2021 18:45:16

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:15
User entered empty.	System	01 Feb 2021 18:45:16

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:31:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 08:06:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 08:06:45
Data point term sent to Coder	System	01 Feb 2021 18:46:09
User entered 'Ciprofloxacin'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:31:30
User entered 'Sepsis'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered '500'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:31:33
User entered '22 Jan 2021'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered '0'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered '31 Jan 2021' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:18
User entered empty.	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:36:55
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User entered '2'	System	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:08:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User entered '1'	System	01 Feb 2021 18:46:00

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:19
User entered '804 (804)'	System	01 Feb 2021 18:46:00

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 21:35:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 21:35:04
Data point term sent to Coder	System	17 Feb 2021 21:34:20
User entered 'Tylenol'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'No (N)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'Sepsis'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered '1000'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50



US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered empty.	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered empty.	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered empty.	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered '18 Jan 2021'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered '0'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'No (N)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered '18 Jan 2021'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:08:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 21:37:20
User entered 'No (N)'	Matthew Musikanth (b) (4)	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User entered empty.	System	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User entered empty.	System	17 Feb 2021 21:33:50

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:24
User entered empty.	System	17 Feb 2021 21:33:50

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ANTIBIOTICS, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:12:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:12:47
Data point term sent to Coder	System	02 Mar 2021 21:57:36
User entered 'ciprofloxacin'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'prostatitis'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '500'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'mg (mg)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'twice daily (BID)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

US3112071

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:08:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered empty.	Natalie Moy (b) (4)	02 Mar 2021 21:56:38



**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '04 Feb 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '0'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered '22 Feb 2021'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Natalie Moy (b) (4)	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User entered '2'	System	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User entered '1'	System	02 Mar 2021 21:56:38

**US3112071**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:08:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:03:28
User entered '804 (804)'	System	02 Mar 2021 21:56:38



US3112071

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:08:25**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
User entered 'No (N)'	Matthew Musikanth (b) (4)	18 Feb 2021 18:38:14

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'USA-US062-2021-MRNA-1273-P301000008'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46



US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Laurie'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Han-Conrad'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'San Diego'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'CA'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '92108'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:32:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
User entered 'US'	System	25 Jan 2021 16:53:07



**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 15:33:05
User entered '1'	System	25 Jan 2021 16:53:07

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'USA-US062-2021-MRNA-1273-P301000008'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46



US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Laurie'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Han-Conrad'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'San Diego'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'CA'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '92108'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:32:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
User entered 'US'	System	25 Jan 2021 16:53:07



**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 15:33:05
User entered '1'	System	25 Jan 2021 16:53:07

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:08:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
User entered '25/Jan/2021 11:53'	System	25 Jan 2021 16:53:07

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:08:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:32:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 16:53:07

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'USA-US062-2021-MRNA-1273-P301000008'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Yes (Y)'	System	25 Jan 2021 16:52:46



US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'No (N)'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Laurie'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'Han-Conrad'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'San Diego'	System	25 Jan 2021 16:52:46

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered 'CA'	System	25 Jan 2021 16:52:46



**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 16:52:59
User entered '92108'	System	25 Jan 2021 16:52:46

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:08:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:32:52
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:30:28
User entered 'US'	System	25 Jan 2021 16:53:07

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:08:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 15:33:05
User entered '1'	System	25 Jan 2021 16:53:07

**US3112071**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:08:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:18:41
User entered '02/Feb/2021 15:33'	System	02 Feb 2021 15:33:05

US3112071

Folder: SAE USA-US062-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:08:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:50:41
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 19:18:43
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 15:33:05