

US3112210 (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

US3112210

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

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Participant ID

US3112210

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

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US3112210

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:00:03

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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 17:00:03

Generated On: 09 Jun 2021 15:09:52

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input checked="" type="radio"/> Male <input 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 17:00:03

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 17:00:03

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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 17:00:03

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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 17:00:03

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Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
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 17:00:03

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Condition	BILATERAL BREAST AUGMENTATION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:00:03

Generated On: 09 Jun 2021 15:09:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:39 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:39
Height ( <i>xxx.x</i> )	68.5 in
Weight ( <i>xxx.x</i> )	226 lb
BMI ( <i>xxx.x</i> )	33.93417 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 17:00:03

Generated On: 09 Jun 2021 15:09:52

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 17:00:03

Generated On: 09 Jun 2021 15:09:52

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☒  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:00:03

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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** RETIRED

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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 17:00:03

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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 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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 21:04:36

Generated On: 09 Jun 2021 15:09:52

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103294

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:39
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 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 21:04:36

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	12:49 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:49
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 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 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 AUG 2020

What was the treatment time? (00:00-23:59) 12:16 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 12:16

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 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	12:02 (24 HR)
Collection date and time (derived)	12 AUG 2020 12:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:54	12 AUG 2020 11:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 12 AUG 2020 12:49

PC Open Date & Time 12 AUG 2020 12:36

PC Close Date & Time 12 AUG 2020 15:06

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	12 AUG 2020 16:18
PC Open Date & Time	12 AUG 2020 16:01
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 AUG 2020 18:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

14 AUG 2020 17:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

15 AUG 2020 20:06

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 AUG 2020 15:32

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

17 AUG 2020 21:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

18 AUG 2020 22:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:50

PC Open Date & Time

12 AUG 2020 12:36

PC Close Date & Time

12 AUG 2020 15:06

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 16:18

PC Open Date & Time

12 AUG 2020 16:01

PC Close Date & Time

13 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 20:07

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 15:32

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:35

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 22:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59



US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 12:51
PC Open Date & Time	12 AUG 2020 12:36
PC Close Date & Time	12 AUG 2020 15:06

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 16:19
PC Open Date & Time	12 AUG 2020 16:01
PC Close Date & Time	13 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 17:12
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59



US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:07
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 15:34
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:36
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

54 of 1981

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59



US3112210

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

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*

US3112210

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:43:46

Generated On: 09 Jun 2021 15:09:52

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*

US3112210

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:43:46

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112210

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:36
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3112210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 9 SEP 2020

What was the treatment time? (00:00-23:59) 11:02 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 11:02

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

US3112210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

10:10 (24 HR)

Collection date and time (derived)

9 SEP 2020 10:10

US3112210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:08	9 SEP 2020 10:08
Nasopharyngeal Swab 2	No		

US3112210

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 11:36

PC Open Date & Time

09 SEP 2020 11:22

PC Close Date & Time

09 SEP 2020 13:52

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	09 SEP 2020 20:39
PC Open Date & Time	09 SEP 2020 14:47
PC Close Date & Time	10 SEP 2020 11:59



US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 07:57

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 17:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

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**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

97.2 °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

14 SEP 2020 06:45

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PC Open Date & Time

13 SEP 2020 12:00

---

PC Close Date & Time

14 SEP 2020 11:59

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US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 07:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

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**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

98.6 °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

15 SEP 2020 18:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 11:39

PC Open Date & Time

09 SEP 2020 11:22

PC Close Date & Time

09 SEP 2020 13:52

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 20:40

PC Open Date & Time

09 SEP 2020 14:47

PC Close Date & Time

10 SEP 2020 11:59



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 19:22

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 07:57

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 17:25

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 06:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 07:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 18:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 11:39
PC Open Date & Time	09 SEP 2020 11:22
PC Close Date & Time	09 SEP 2020 13:52



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 20:40
PC Open Date & Time	09 SEP 2020 14:47
PC Close Date & Time	10 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:22
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 07:58
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 1981

EAB) (1725)

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:26
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 1981

EAB) (1725)

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 06:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 07:22
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 1981

EAB) (1725)

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:06
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112210

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:43:47

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	9:52 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 9:52
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3112210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	10:08 (24 HR)
Collection date and time (derived)	7 OCT 2020 10:08



US3112210

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:04:36

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**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

12 OCT 2020 06:50:35

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3112210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**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

19 OCT 2020 06:55:25

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3112210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**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

27 OCT 2020 09:03:50

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3112210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 06:23:34

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3112210

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**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

16 NOV 2020 06:36:50

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 00:02:17

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 02:36:46

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59



US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 07:42:23

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 14:57:25

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:44:03

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 06:55:22

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 12:26:33

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 07:21:47

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 12:01:26

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	22 JAN 2021 10:15:22
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59



US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 06:11:58

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 12:07:00

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 07:05:03

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 07:06:53
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 12:03:25

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:03:14

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 07:11:03

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 06:59:59

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59



US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 10:04:08

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 12:27:48
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 05:57:12

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 06:54:08

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 05:12:52

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 271

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 292

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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 ☐



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 306

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 383

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 439

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

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**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 481

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 495

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 530

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 544

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 565

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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15 MAR 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

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15 APR 2022 00:01

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19 APR 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 628

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 635

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 642

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 684

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 698

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 705

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 712

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 747

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 761

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 768

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 775

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

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

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

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



**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3112210**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3112210

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:52

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

**US3112210**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 15:09:52**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:03:39



US3112210

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:50:31

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:50:31

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 DEC 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 JAN 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3112210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 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	VISIT4
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US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:39
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3112210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

10:11 (24 HR)

Collection date and time (derived)

24 FEB 2021 10:11

US3112210

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 APR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112210**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3112210**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3112210**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:09:52**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3112210**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 15:09:52**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 24 FEB 2021

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☒

Folder OID UNBLND\_DECIDE

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Date of updated informed consent ( <i>dd MMM yyyy</i> )	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	24 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	24 FEB 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:39
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	24 FEB 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:56
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 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)	74 mmHg
Diastolic Blood Pressure units	MMHG



US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 10:25

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

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

10:11 (24 HR)

Collection date and time (derived)

24 FEB 2021 10:11

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	24 FEB 2021
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Collection time (00:00 - 23:59)	10:08
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Collection Date and Time (derived)	24 FEB 2021 10:08
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US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3112210

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 09:21
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 10:28
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3112210

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3112210

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify \_\_\_\_\_

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 MAR 2021

What was the treatment time? (00:00-23:59) 09:57 (24 HR)

Treatment Date and Time (derived) 23 MAR 2021 09:57

Which arm was used to give treatment? Left Arm ☒  
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3112210

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112210

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:15:05

Generated On: 09 Jun 2021 15:09:52

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 MAR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3112210

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3112210**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_



US3112210

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3112210

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

**US3112210**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3112210

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:25:05

Generated On: 09 Jun 2021 15:09:52

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

AEID	USA-US062-2021-MRNA-1273-P30 1000007
Adverse event	ENDOMETRIAL CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 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)	27 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

PT. SEEN AT PCP FOR  
DIAGNOSTICS AND WAS  
RECENTLY DIAGNOSED WITH  
ENDOMETRIAL CANCER.  
SUBJECT HAS HAD A  
HYSTERECTOMY DONE ON  
27JAN2021.

SUBJECT HAD A PHYSICAL  
EXAM, AND A CXR ON THE  
22JAN2021. THEY HAD AN  
ABDOMEN CT ON THE  
20JAN2021. THEY HAD A LEFT  
SPINE MRI ON THE 20JAN2021.  
ENDOMETRIAL CANCER  
DETERMINED BY UTERINE  
BIOPSY. PLANNED PROCEDURE  
FOR TOTAL LAPAROSCOPIC  
HYSTERECTOMY BILATERAL  
SALPINGO OOPHORECTOMY  
WITH STAGE, BILATERAL  
PELVIC LYMPH NODE  
DISSECTION BILATERAL  
URETROLYSIS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

AEID	
Adverse event	BASAL CELL CARCINOMA
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)	19 MAR 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 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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US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:07:46

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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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 440

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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EAB) (1725)

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US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (2)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA 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 ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Name of Medication GABAPENTIN

Prophylaxis Yes ☒  
No ☐

Indication PRE AND POST OPERATIVE  
PAIN RELIEF (ENDOMETRIAL  
CANCER TREATMENT)

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 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)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication STOOL SOFTENER POST OP  
(ENDOMETRIAL CANCER  
TREATMENT)

Dose per administration 200

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 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)		3 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:07:46

Generated On: 09 Jun 2021 15:09:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 JAN 2021	LAPAROSCOPIC HYSTERECTOMY BILATERAL SALPINGO OOPHORECTOMY WITH STAGE, BILATERAL PELVIC LYMPH NODE DISSECTION BILATERAL URETROLYSIS.	Adverse Event	
19 MAR 2021	EXCISIONAL BIOPSY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:09:52

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:09:52

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	25/JAN/2021 14:33
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



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	10/FEB/2021 12:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:28
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

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	17/FEB/2021 12:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:57
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

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 21:15:04

Generated On: 09 Jun 2021 15:09:52

SAEID	USA-US062-2021-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input 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)	6
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:39
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

US3112210 (Prod: Medical Center For Clinical Research - M3 Wake Research)

**US3112210**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:09:52**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'US3112210'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:54:28

**US3112210**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:47



US3112210

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:54:29

**US3112210**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[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 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	12 Aug 2020 19:47:47

**US3112210**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'SCRN'	System	12 Aug 2020 19:47:47

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:54:30

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '62'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'YEARS'	System	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '62'	System	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29



**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

US3112210

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29



**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:09:52**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:29

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '12 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'Aug 2020'	System	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '2020'	System	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56



**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:47:56

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:54:29

**US3112210**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:09:52**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'I'	System	12 Aug 2020 19:48:01

**US3112210**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:09:52**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	12 Aug 2020 19:48:01

**US3112210**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 15:09:52**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Feb 2021 17:18:30
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 23:51:13

US3112210

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Feb 2021 17:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:20:37
Data point term sent to Coder	System	09 Feb 2021 17:19:23
User entered 'presbyopia'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'un UNK 2013'	Brenda Grande (b) (4)	09 Feb 2021 17:18:53



**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	Brenda Grande (b) (4)	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	Brenda Grande (b) (4)	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'Jan 2013'	System	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '2013'	System	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered empty.	System	09 Feb 2021 17:18:53

**US3112210**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered empty.	System	09 Feb 2021 17:18:53



US3112210

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:21:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 17:21:35
Data point term sent to Coder	System	09 Feb 2021 17:20:23
User entered 'BILATERAL breast augmentation'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'UN UNK 2004'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'UN UNK 2004'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	Brenda Grande (b) (4)	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'Jan 2004'	System	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '2004'	System	09 Feb 2021 17:20:06



**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'Jan 2004'	System	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '2004'	System	09 Feb 2021 17:20:06

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '11:39'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered '12 Aug 2020 11:39'	System	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '68.5' in	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12
DataPoint set to visible.	System	12 Aug 2020 19:48:01

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '226' lb	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12
DataPoint set to visible.	System	12 Aug 2020 19:48:01



**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
Amendment Manager: User entered '33.93417'	System	16 Sep 2020 23:54:07
User entered '33.9'	System	17 Aug 2020 23:49:12
DataPoint set to visible.	System	12 Aug 2020 19:48:01

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'kg/m2'	System	17 Aug 2020 23:49:12
DataPoint set to visible.	System	12 Aug 2020 19:48:01

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
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)	24 Sep 2020 10:04:49
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 'data updated per query request' (Site from DM).	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:44:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:44:11
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)	21 Aug 2020 15:30:54
User entered '98.6' F	(b) (4), (b) (6)	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:44:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:44:11
User entered '70'	(b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'bpm'	System	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:44:11
User entered '14'	(b) (4), (b) (6)	17 Aug 2020 23:49:12



**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'breaths/min'	System	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:44:11
User entered '116'	(b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'mmHg'	System	17 Aug 2020 23:49:12

US3112210

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:44:11
User entered '76'	(b) (4), (b) (6)	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User entered 'mmHg'	System	17 Aug 2020 23:49:12

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 11:50:38

**US3112210**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38

US3112210

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:54



US3112210

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
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)	11 Sep 2020 14:13:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 18:11:02
User entered '12 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 23:50:54

**US3112210**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

US3112210

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:52

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

**US3112210**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:09:52**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

**US3112210**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:09:52**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

US3112210

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:52

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

**US3112210**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:09:52**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

US3112210

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:52

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31



**US3112210**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:09:52**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:47:31

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**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 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**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 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

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 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09



US3112210

Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

**US3112210**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:09:52**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'Retired'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

**US3112210**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:09:52**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09



US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

US3112210

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:50:38
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:00:04
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:48:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:51:22

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:51:22



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:51:22

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'VISIT1'	System	17 Aug 2020 23:51:22

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:59:15

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:58:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:58:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 18:59:15
User entered '103294' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:59:15

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 18:59:15

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:42

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:09:52**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:42



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:09:52**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:09:52**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:46:42

US3112210

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:52

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:27:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:51:37

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 23:50:09



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '11:39'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '12 Aug 2020 11:39'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'bpm'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'breaths/min'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '116'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '76'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09



US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 03:58:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 23:50:09
User entered '12:49'	(b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '12 Aug 2020 12:49'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09



US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '68'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'bpm'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'breaths/min'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '132'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '90'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:09



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Aug 2020 23:50:09

US3112210

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:22

US3112210

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:22

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	12 Aug 2020 19:48:34
	(b) (4)	

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) Matthew Musikanth	12 Aug 2020 19:48:34
	(b) (4)	

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 19:48:34

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 19:48:34

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) Matthew Musikanth	12 Aug 2020 19:48:34
	(b) (4)	



US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12:16'	(b) (4) Matthew Musikanth	12 Aug 2020 19:48:34
	(b) (4)	

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '12 Aug 2020 12:16'	System	12 Aug 2020 19:48:34

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Matthew Musikanth	12 Aug 2020 19:48:34
	(b) (4)	

US3112210

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'ONCE'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:33

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:33

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12:02'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:33



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '12 Aug 2020 12:02'	System	17 Aug 2020 23:50:33

US3112210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Aug 2020 23:50:42

US3112210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '11:54'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '12 Aug 2020 11:54'	System	17 Aug 2020 23:50:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Aug 2020 23:50:42

US3112210

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:42



**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:50:42

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered empty.	System	17 Aug 2020 23:50:42

US3112210

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 23:51:26

**US3112210**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	17 Aug 2020 23:51:26

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:49:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4543ab40-92ab-47fb-bcd5-fc53ad9c80df' User entered 'Yes (Y)'	System	12 Aug 2020 19:49:49
	System	12 Aug 2020 19:49:49

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:49:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4543ab40-92ab-47fb-bcd5-fc53ad9c80df' User entered '98.2'	System	12 Aug 2020 19:49:49
	System	12 Aug 2020 19:49:49

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:49:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4543ab40-92ab-47fb-bcd5-fc53ad9c80df' User entered 'No (N)'	System	12 Aug 2020 19:49:49
	System	12 Aug 2020 19:49:49



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:49:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4543ab40-92ab-47fb-bcd5-fc53ad9c80df' User entered '12 Aug 2020 12:49'	System	12 Aug 2020 19:49:49
	System	12 Aug 2020 19:49:49

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Aug 2020 12:36'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:17:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405e0c36-448c-4f30-bd84-8d4f44de77a7' User entered 'Yes (Y)'	System	12 Aug 2020 23:18:25
	System	12 Aug 2020 23:18:25

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405e0c36-448c-4f30-bd84-8d4f44de77a7' User entered '98.0'	System	12 Aug 2020 23:18:25
	System	12 Aug 2020 23:18:25

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405e0c36-448c-4f30-bd84-8d4f44de77a7'	System	12 Aug 2020 23:18:25
User entered 'No (N)'	System	12 Aug 2020 23:18:25

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405e0c36-448c-4f30-bd84-8d4f44de77a7' User entered '12 Aug 2020 16:18'	System	12 Aug 2020 23:18:25
	System	12 Aug 2020 23:18:25



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Aug 2020 16:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 2'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:00:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '342a8c3f-218b-4084-85b5-077761e29ada' User entered 'Yes (Y)'	System	14 Aug 2020 01:01:14
	System	14 Aug 2020 01:01:14

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:00:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '342a8c3f-218b-4084-85b5-077761e29ada' User entered '97.9'	System	14 Aug 2020 01:01:14
	System	14 Aug 2020 01:01:14

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '342a8c3f-218b-4084-85b5-077761e29ada' User entered 'No (N)'	System	14 Aug 2020 01:01:14
	System	14 Aug 2020 01:01:14

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '342a8c3f-218b-4084-85b5-077761e29ada' User entered '13 Aug 2020 18:01'	System	14 Aug 2020 01:01:14
	System	14 Aug 2020 01:01:14

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:48:34



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 3'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:10:45', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bc7d2cc0-3fc2-4df9-a5fe-0f75556d5be5' User entered 'Yes (Y)'	System	15 Aug 2020 00:11:05
	System	15 Aug 2020 00:11:05

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:10:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bc7d2cc0-3fc2-4df9-a5fe-0f75556d5be5' User entered '98.1'	System	15 Aug 2020 00:11:05
	System	15 Aug 2020 00:11:05

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:10:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bc7d2cc0-3fc2-4df9-a5fe-0f75556d5be5'	System	15 Aug 2020 00:11:05
User entered 'No (N)'	System	15 Aug 2020 00:11:05

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bc7d2cc0-3fc2-4df9-a5fe-0f75556d5be5' User entered '14 Aug 2020 17:11'	System	15 Aug 2020 00:11:05
	System	15 Aug 2020 00:11:05

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:48:34



US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 4'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:06:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd277f3eb-c997-4cf2-9339-e78100ad7b29' User entered 'Yes (Y)'	System	16 Aug 2020 03:06:59
	System	16 Aug 2020 03:06:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:06:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd277f3eb-c997-4cf2-9339-e78100ad7b29' User entered '97.5'	System	16 Aug 2020 03:06:59
	System	16 Aug 2020 03:06:59

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:06:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd277f3eb-c997-4cf2-9339-e78100ad7b29' User entered 'No (N)'	System	16 Aug 2020 03:06:59
	System	16 Aug 2020 03:06:59

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:06:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd277f3eb-c997-4cf2-9339-e78100ad7b29' User entered '15 Aug 2020 20:06'	System	16 Aug 2020 03:06:59
	System	16 Aug 2020 03:06:59

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 5'	System	12 Aug 2020 19:48:34



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:31:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8be2d94b-f12f-43ff-b78d-44ac7edfb84a' User entered 'Yes (Y)'	System	16 Aug 2020 22:32:19
	System	16 Aug 2020 22:32:19

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8be2d94b-f12f-43ff-b78d-44ac7edfb84a' User entered '97.1'	System	16 Aug 2020 22:32:19
	System	16 Aug 2020 22:32:19

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:10', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8be2d94b-f12f-43ff-b78d-44ac7edfb84a'	System	16 Aug 2020 22:32:19
User entered 'No (N)'	System	16 Aug 2020 22:32:19

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8be2d94b-f12f-43ff-b78d-44ac7edfb84a' User entered '16 Aug 2020 15:32'	System	16 Aug 2020 22:32:19
	System	16 Aug 2020 22:32:19

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 6'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:34:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7b64a1c4-0f61-4042-b7d9-7e5c376e2e69'	System	18 Aug 2020 04:35:22
User entered 'Yes (Y)'	System	18 Aug 2020 04:35:22



US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:06', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7b64a1c4-0f61-4042-b7d9-7e5c376e2e69' User entered '97.6'	System	18 Aug 2020 04:35:22
	System	18 Aug 2020 04:35:22

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:09', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7b64a1c4-0f61-4042-b7d9-7e5c376e2e69'	System	18 Aug 2020 04:35:22
User entered 'No (N)'	System	18 Aug 2020 04:35:22

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7b64a1c4-0f61-4042-b7d9-7e5c376e2e69'	System	18 Aug 2020 04:35:22
User entered '17 Aug 2020 21:35'	System	18 Aug 2020 04:35:22

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 7'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:16:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405a3f3a-bb69-4c90-a739-7f9975afadfd' User entered 'Yes (Y)'	System	19 Aug 2020 05:17:05
	System	19 Aug 2020 05:17:05

US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:16:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405a3f3a-bb69-4c90-a739-7f9975afadfd' User entered '97.6'	System	19 Aug 2020 05:17:05
	System	19 Aug 2020 05:17:05



US3112210

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:16:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405a3f3a-bb69-4c90-a739-7f9975afadfd' User entered 'No (N)'	System	19 Aug 2020 05:17:05
	System	19 Aug 2020 05:17:05

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '405a3f3a-bb69-4c90-a739-7f9975afadfd' User entered '18 Aug 2020 22:17'	System	19 Aug 2020 05:17:05
	System	19 Aug 2020 05:17:05

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:50:14', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bca8ca2f-2f74-4f66-980c-7962f539e03d' User entered 'None (1)'	System	12 Aug 2020 19:50:55
	System	12 Aug 2020 19:50:55

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:50:21', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bca8ca2f-2f74-4f66-980c-7962f539e03d' User entered 'No (N)'	System	12 Aug 2020 19:50:55
	System	12 Aug 2020 19:50:55

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:50:34', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bca8ca2f-2f74-4f66-980c-7962f539e03d' User entered 'No (N)'	System	12 Aug 2020 19:50:55
	System	12 Aug 2020 19:50:55



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:50:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bca8ca2f-2f74-4f66-980c-7962f539e03d' User entered 'None (1)'	System	12 Aug 2020 19:50:55
	System	12 Aug 2020 19:50:55

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:50:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bca8ca2f-2f74-4f66-980c-7962f539e03d' User entered '12 Aug 2020 12:50'	System	12 Aug 2020 19:50:55
	System	12 Aug 2020 19:50:55

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 12:36'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:30', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '76520ebe-bbb2-45cd-a9b3-2d77c82e284e' User entered 'None (1)'	System	12 Aug 2020 23:18:59
	System	12 Aug 2020 23:18:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '76520ebe-bbb2-45cd-a9b3-2d77c82e284e' User entered 'No (N)'	System	12 Aug 2020 23:18:59
	System	12 Aug 2020 23:18:59

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:35', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '76520ebe-bbb2-45cd-a9b3-2d77c82e284e' User entered 'No (N)'	System	12 Aug 2020 23:18:59
	System	12 Aug 2020 23:18:59



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:49', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '76520ebe-bbb2-45cd-a9b3-2d77c82e284e' User entered 'None (1)'	System	12 Aug 2020 23:18:59
	System	12 Aug 2020 23:18:59

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:18:57', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '76520ebe-bbb2-45cd-a9b3-2d77c82e284e' User entered '12 Aug 2020 16:18'	System	12 Aug 2020 23:18:59
	System	12 Aug 2020 23:18:59

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 16:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 2'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:21', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '78c48356-1d33-4500-9ae4-893cf945383a' User entered 'None (1)'	System	14 Aug 2020 01:01:43
	System	14 Aug 2020 01:01:43

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:24', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '78c48356-1d33-4500-9ae4-893cf945383a' User entered 'No (N)'	System	14 Aug 2020 01:01:43
	System	14 Aug 2020 01:01:43

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:27', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '78c48356-1d33-4500-9ae4-893cf945383a' User entered 'No (N)'	System	14 Aug 2020 01:01:43
	System	14 Aug 2020 01:01:43



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '78c48356-1d33-4500-9ae4-893cf945383a' User entered 'None (1)'	System	14 Aug 2020 01:01:43
	System	14 Aug 2020 01:01:43

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:39', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '78c48356-1d33-4500-9ae4-893cf945383a' User entered '13 Aug 2020 18:01'	System	14 Aug 2020 01:01:43
	System	14 Aug 2020 01:01:43

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 3'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2e97ad2-6bf8-463a-8a22-1cef7e63c211'	System	15 Aug 2020 00:11:41
User entered 'None (1)'	System	15 Aug 2020 00:11:41

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2e97ad2-6bf8-463a-8a22-1cef7e63c211'	System	15 Aug 2020 00:11:41
User entered 'No (N)'	System	15 Aug 2020 00:11:41

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2e97ad2-6bf8-463a-8a22-1cef7e63c211'	System	15 Aug 2020 00:11:41
User entered 'No (N)'	System	15 Aug 2020 00:11:41



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2e97ad2-6bf8-463a-8a22-1cef7e63c211'	System	15 Aug 2020 00:11:41
User entered 'None (1)'	System	15 Aug 2020 00:11:41

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2e97ad2-6bf8-463a-8a22-1cef7e63c211' User entered '14 Aug 2020 17:11'	System	15 Aug 2020 00:11:41
	System	15 Aug 2020 00:11:41

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 4'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5091435e-209e-4880-b8fc-06aaa2f5a1ac'	System	16 Aug 2020 03:07:28
User entered 'None (1)'	System	16 Aug 2020 03:07:28

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5091435e-209e-4880-b8fc-06aaa2f5a1ac' User entered 'No (N)'	System	16 Aug 2020 03:07:28
	System	16 Aug 2020 03:07:28

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:19', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5091435e-209e-4880-b8fc-06aaa2f5a1ac' User entered 'No (N)'	System	16 Aug 2020 03:07:28
	System	16 Aug 2020 03:07:28



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5091435e-209e-4880-b8fc-06aaa2f5a1ac'	System	16 Aug 2020 03:07:28
User entered 'None (1)'	System	16 Aug 2020 03:07:28

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5091435e-209e-4880-b8fc-06aaa2f5a1ac' User entered '15 Aug 2020 20:07'	System	16 Aug 2020 03:07:28
	System	16 Aug 2020 03:07:28

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 5'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:28', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'add39363-2e29-4a04-bf6e-88fc404e3cb6'	System	16 Aug 2020 22:33:03
User entered 'None (1)'	System	16 Aug 2020 22:33:03

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'add39363-2e29-4a04-bf6e-88fc404e3cb6'	System	16 Aug 2020 22:33:03
User entered 'No (N)'	System	16 Aug 2020 22:33:03

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'add39363-2e29-4a04-bf6e-88fc404e3cb6'	System	16 Aug 2020 22:33:03
User entered 'No (N)'	System	16 Aug 2020 22:33:03



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:54', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'add39363-2e29-4a04-bf6e-88fc404e3cb6'	System	16 Aug 2020 22:33:03
User entered 'None (1)'	System	16 Aug 2020 22:33:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:32:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'add39363-2e29-4a04-bf6e-88fc404e3cb6'	System	16 Aug 2020 22:33:03
User entered '16 Aug 2020 15:32'	System	16 Aug 2020 22:33:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 6'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '96d49574-35b0-4acf-943f-884be89b9df7'	System	18 Aug 2020 04:35:47
User entered 'None (1)'	System	18 Aug 2020 04:35:47

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '96d49574-35b0-4acf-943f-884be89b9df7'	System	18 Aug 2020 04:35:47
User entered 'No (N)'	System	18 Aug 2020 04:35:47

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '96d49574-35b0-4acf-943f-884be89b9df7' User entered 'No (N)'	System	18 Aug 2020 04:35:47
	System	18 Aug 2020 04:35:47



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:34', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '96d49574-35b0-4acf-943f-884be89b9df7'	System	18 Aug 2020 04:35:47
User entered 'None (1)'	System	18 Aug 2020 04:35:47

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '96d49574-35b0-4acf-943f-884be89b9df7' User entered '17 Aug 2020 21:35'	System	18 Aug 2020 04:35:47
	System	18 Aug 2020 04:35:47

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 7'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2ed4633-2662-473e-be5d-31a84dab774d' User entered 'None (1)'	System	19 Aug 2020 05:17:24
	System	19 Aug 2020 05:17:24

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2ed4633-2662-473e-be5d-31a84dab774d' User entered 'No (N)'	System	19 Aug 2020 05:17:24
	System	19 Aug 2020 05:17:24

US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2ed4633-2662-473e-be5d-31a84dab774d' User entered 'No (N)'	System	19 Aug 2020 05:17:24
	System	19 Aug 2020 05:17:24



US3112210

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

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 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2ed4633-2662-473e-be5d-31a84dab774d'	System	19 Aug 2020 05:17:24
User entered 'None (1)'	System	19 Aug 2020 05:17:24

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a2ed4633-2662-473e-be5d-31a84dab774d' User entered '18 Aug 2020 22:17'	System	19 Aug 2020 05:17:24
	System	19 Aug 2020 05:17:24

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:06', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:09', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56



US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:12', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:24', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'None (0)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered 'No (N)'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T12:51:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9571584e-6029-4938-892f-a982dcc8e2b9' User entered '12 Aug 2020 12:51'	System	12 Aug 2020 19:51:56
	System	12 Aug 2020 19:51:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 12:36'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 19:48:34



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:20', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'None (0)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:32', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered 'No (N)'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-12T16:19:38', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ff57a596-f81a-4dfd-b700-d2a9eb03942b' User entered '12 Aug 2020 16:19'	System	12 Aug 2020 23:19:40
	System	12 Aug 2020 23:19:40



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '12 Aug 2020 16:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 2'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:01:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:02:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:02:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'None (0)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:02:10', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798' User entered 'No (N)'	System	14 Aug 2020 01:02:18
	System	14 Aug 2020 01:02:18

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-13T18:02:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6284cdf8-aa40-4353-974c-064f37ca9798'	System	14 Aug 2020 01:02:18
User entered '13 Aug 2020 18:02'	System	14 Aug 2020 01:02:18

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 3'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:11:57', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:12:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:12:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'None (0)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:12:06', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered 'No (N)'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-14T17:12:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6def8b49-5e5b-456e-8531-f7c37bdeb87e' User entered '14 Aug 2020 17:12'	System	15 Aug 2020 00:12:15
	System	15 Aug 2020 00:12:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 19:48:34



US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 4'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:35', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered 'None (0)'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740'	System	16 Aug 2020 03:07:56
User entered 'No (N)'	System	16 Aug 2020 03:07:56



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-15T20:07:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd2910ed5-81a7-49aa-b8d7-62ae5894f740' User entered '15 Aug 2020 20:07'	System	16 Aug 2020 03:07:56
	System	16 Aug 2020 03:07:56

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 5'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:32', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:38', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'None (0)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:33:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered 'No (N)'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-16T15:34:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c40ae486-e750-4839-8383-15148391efca' User entered '16 Aug 2020 15:34'	System	16 Aug 2020 22:34:03
	System	16 Aug 2020 22:34:03

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 6'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:35:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:36:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'None (0)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:36:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered 'No (N)'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-17T21:36:10', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '84f5e9cf-7b56-43c9-91a6-9ec66e7daa1f' User entered '17 Aug 2020 21:36'	System	18 Aug 2020 04:36:15
	System	18 Aug 2020 04:36:15

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 19:48:34



**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 7'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2' User entered 'None (0)'	System	19 Aug 2020 05:17:49
	System	19 Aug 2020 05:17:49

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2'	System	19 Aug 2020 05:17:49
User entered 'None (0)'	System	19 Aug 2020 05:17:49

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2'	System	19 Aug 2020 05:17:49
User entered 'None (0)'	System	19 Aug 2020 05:17:49

US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2' User entered 'None (0)'	System	19 Aug 2020 05:17:49
	System	19 Aug 2020 05:17:49

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2' User entered 'None (0)'	System	19 Aug 2020 05:17:49
	System	19 Aug 2020 05:17:49

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:38', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2'	System	19 Aug 2020 05:17:49
User entered 'None (0)'	System	19 Aug 2020 05:17:49



US3112210

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2'	System	19 Aug 2020 05:17:49
User entered 'No (N)'	System	19 Aug 2020 05:17:49

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-08-18T22:17:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '64da426a-39bf-47f0-b565-76f7d7c111f2' User entered '18 Aug 2020 22:17'	System	19 Aug 2020 05:17:49
	System	19 Aug 2020 05:17:49

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:59:33
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:51:28

**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:51:28

**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:51:28

**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:51:28



**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:51:32

**US3112210**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	19 Aug 2020 23:51:32

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	09 Sep 2020 20:14:38

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered '26 Aug 2020'	Karen Mylerberg (b) (4)	09 Sep 2020 20:14:38

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	09 Sep 2020 20:14:38

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	Karen Mylerberg (b) (4)	09 Sep 2020 20:14:38

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:10:41

**US3112210**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	09 Sep 2020 18:10:41



**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'No (N)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:25

**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:25

**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:25

**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:25

**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:10:47

**US3112210**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	09 Sep 2020 18:10:47

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:02

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:02



**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:02

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'VISIT2'	System	09 Sep 2020 18:11:02

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '10:05'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '9 Sep 2020 10:05'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26



US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'bpm'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '15'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'breaths/min'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '136'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Sep 2020 14:31:26



US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '11:36'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '9 Sep 2020 11:36'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26



US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '76'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'bpm'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'breaths/min'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '130'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Sep 2020 14:31:26



US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	17 Sep 2020 14:31:26

US3112210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 16:35:53
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 14:31:35

US3112210

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 16:35:53
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 14:31:35

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 18:11:20



US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '11:02'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '9 Sep 2020 11:02'	System	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'ONCE'	System	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 18:11:20

US3112210

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:51

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:51



**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '10:10'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:31:51

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '9 Sep 2020 10:10'	System	17 Sep 2020 14:31:51

US3112210

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '10:08'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '9 Sep 2020 10:08'	System	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 14:32:07



**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:32:07

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered empty.	System	17 Sep 2020 14:32:07

US3112210

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:11:26

**US3112210**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	09 Sep 2020 18:11:26

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:36:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '39c0e502-4256-4579-9956-f13f544a1ab9' User entered 'Yes (Y)'	System	09 Sep 2020 18:36:51
	System	09 Sep 2020 18:36:51

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:36:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '39c0e502-4256-4579-9956-f13f544a1ab9' User entered '98.4'	System	09 Sep 2020 18:36:51
	System	09 Sep 2020 18:36:51



US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:36:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '39c0e502-4256-4579-9956-f13f544a1ab9' User entered 'No (N)'	System	09 Sep 2020 18:36:51
	System	09 Sep 2020 18:36:51

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:36:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '39c0e502-4256-4579-9956-f13f544a1ab9' User entered '09 Sep 2020 11:36'	System	09 Sep 2020 18:36:51
	System	09 Sep 2020 18:36:51

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 11:22'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 13:52'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bbd3a907-53f4-4fae-be6d-2421e0d51f43'	System	10 Sep 2020 03:39:51
User entered 'Yes (Y)'	System	10 Sep 2020 03:39:51

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bbd3a907-53f4-4fae-be6d-2421e0d51f43'	System	10 Sep 2020 03:39:51
User entered '98.4'	System	10 Sep 2020 03:39:51

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:43', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bbd3a907-53f4-4fae-be6d-2421e0d51f43'	System	10 Sep 2020 03:39:51
User entered 'No (N)'	System	10 Sep 2020 03:39:51



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:49', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bbd3a907-53f4-4fae-be6d-2421e0d51f43'	System	10 Sep 2020 03:39:51
User entered '09 Sep 2020 20:39'	System	10 Sep 2020 03:39:51

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 14:47'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 2'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ad3ffb11-418a-4af6-b615-09ead4574bc8'	System	11 Sep 2020 02:21:40
User entered 'Yes (Y)'	System	11 Sep 2020 02:21:40

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ad3ffb11-418a-4af6-b615-09ead4574bc8' User entered '97.2'	System	11 Sep 2020 02:21:40
	System	11 Sep 2020 02:21:40

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ad3ffb11-418a-4af6-b615-09ead4574bc8'	System	11 Sep 2020 02:21:40
User entered 'No (N)'	System	11 Sep 2020 02:21:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:38', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ad3ffb11-418a-4af6-b615-09ead4574bc8'	System	11 Sep 2020 02:21:40
User entered '10 Sep 2020 19:21'	System	11 Sep 2020 02:21:40



US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:09:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 3'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:56:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd60a9731-2269-4b75-bcef-a396be9d32a0' User entered 'Yes (Y)'	System	12 Sep 2020 14:57:28
	System	12 Sep 2020 14:57:28

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd60a9731-2269-4b75-bcef-a396be9d32a0' User entered '97.4'	System	12 Sep 2020 14:57:28
	System	12 Sep 2020 14:57:28

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd60a9731-2269-4b75-bcef-a396be9d32a0'	System	12 Sep 2020 14:57:28
User entered 'No (N)'	System	12 Sep 2020 14:57:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd60a9731-2269-4b75-bcef-a396be9d32a0' User entered '12 Sep 2020 07:57'	System	12 Sep 2020 14:57:28
	System	12 Sep 2020 14:57:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:11:20



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 4'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:24:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered 'Yes (Y)'	System	13 Sep 2020 00:25:31
	System	13 Sep 2020 00:25:31

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:24:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered '98.5'	System	13 Sep 2020 00:25:31
	System	13 Sep 2020 00:25:31

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:24:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered 'Yes (Y)'	System	13 Sep 2020 00:25:31
	System	13 Sep 2020 00:25:31

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:00:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered '1'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:30:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 00:25:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered '1'	System	13 Sep 2020 00:25:31
User entered '1'	System	13 Sep 2020 00:25:31

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:09:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered '0'	System	13 Sep 2020 00:25:31
	System	13 Sep 2020 00:25:31

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:28', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5ec4a82b-bef6-47a4-87ed-975698ef767a' User entered '12 Sep 2020 17:25'	System	13 Sep 2020 00:25:31
	System	13 Sep 2020 00:25:31



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 5'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '06f312d5-3e0b-40df-8a7c-8e2b06df61fa' User entered 'Yes (Y)'	System	14 Sep 2020 13:45:42
	System	14 Sep 2020 13:45:42

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '06f312d5-3e0b-40df-8a7c-8e2b06df61fa' User entered '97.2'	System	14 Sep 2020 13:45:42
	System	14 Sep 2020 13:45:42

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '06f312d5-3e0b-40df-8a7c-8e2b06df61fa' User entered 'No (N)'	System	14 Sep 2020 13:45:42
	System	14 Sep 2020 13:45:42

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:39', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '06f312d5-3e0b-40df-8a7c-8e2b06df61fa' User entered '14 Sep 2020 06:45'	System	14 Sep 2020 13:45:42
	System	14 Sep 2020 13:45:42

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:11:20



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 6'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:20:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7461929f-459f-4bf8-8ef1-edb11f533510' User entered 'Yes (Y)'	System	15 Sep 2020 14:21:11
	System	15 Sep 2020 14:21:11

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7461929f-459f-4bf8-8ef1-edb11f533510' User entered '97.2'	System	15 Sep 2020 14:21:11
	System	15 Sep 2020 14:21:11

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7461929f-459f-4bf8-8ef1-edb11f533510'	System	15 Sep 2020 14:21:11
User entered 'No (N)'	System	15 Sep 2020 14:21:11

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7461929f-459f-4bf8-8ef1-edb11f533510' User entered '15 Sep 2020 07:21'	System	15 Sep 2020 14:21:11
	System	15 Sep 2020 14:21:11

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 7'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a9449616-b6b6-480f-9131-e1861f334506' User entered 'Yes (Y)'	System	16 Sep 2020 01:05:40
	System	16 Sep 2020 01:05:40

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:20', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a9449616-b6b6-480f-9131-e1861f334506' User entered '98.6'	System	16 Sep 2020 01:05:40
	System	16 Sep 2020 01:05:40

US3112210

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a9449616-b6b6-480f-9131-e1861f334506' User entered 'No (N)'	System	16 Sep 2020 01:05:40
	System	16 Sep 2020 01:05:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:32', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'a9449616-b6b6-480f-9131-e1861f334506' User entered '15 Sep 2020 18:05'	System	16 Sep 2020 01:05:40
	System	16 Sep 2020 01:05:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:38:27', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fbe989c8-4a4c-412b-8b66-de1adf6716'	System	09 Sep 2020 18:39:14
User entered 'None (1)'	System	09 Sep 2020 18:39:14

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:38:57', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fbe989c8-4a4c-412b-8b66-de1adfad6716' User entered 'No (N)'	System	09 Sep 2020 18:39:14
	System	09 Sep 2020 18:39:14

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fbe989c8-4a4c-412b-8b66-de1adf6716'	System	09 Sep 2020 18:39:14
User entered 'No (N)'	System	09 Sep 2020 18:39:14

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:06', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fbe989c8-4a4c-412b-8b66-de1adf6716'	System	09 Sep 2020 18:39:14
User entered 'None (1)'	System	09 Sep 2020 18:39:14

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:12', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fbe989c8-4a4c-412b-8b66-de1adfad6716' User entered '09 Sep 2020 11:39'	System	09 Sep 2020 18:39:14
	System	09 Sep 2020 18:39:14

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 11:22'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 13:52'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:54', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fc9f2cd3-8f04-4ede-9dc0-b867be4b31e3'	System	10 Sep 2020 03:40:09
User entered 'None (1)'	System	10 Sep 2020 03:40:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:39:57', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fc9f2cd3-8f04-4ede-9dc0-b867be4b31e3' User entered 'No (N)'	System	10 Sep 2020 03:40:09
	System	10 Sep 2020 03:40:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fc9f2cd3-8f04-4ede-9dc0-b867be4b31e3' User entered 'No (N)'	System	10 Sep 2020 03:40:09
	System	10 Sep 2020 03:40:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fc9f2cd3-8f04-4ede-9dc0-b867be4b31e3'	System	10 Sep 2020 03:40:09
User entered 'None (1)'	System	10 Sep 2020 03:40:09

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:07', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'fc9f2cd3-8f04-4ede-9dc0-b867be4b31e3' User entered '09 Sep 2020 20:40'	System	10 Sep 2020 03:40:09
	System	10 Sep 2020 03:40:09

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 14:47'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 2'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:42', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '59a45b86-8a9f-4598-b42c-2cc491617a21' User entered 'None (1)'	System	11 Sep 2020 02:22:09
	System	11 Sep 2020 02:22:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '59a45b86-8a9f-4598-b42c-2cc491617a21' User entered 'No (N)'	System	11 Sep 2020 02:22:09
	System	11 Sep 2020 02:22:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:21:49', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '59a45b86-8a9f-4598-b42c-2cc491617a21' User entered 'No (N)'	System	11 Sep 2020 02:22:09
	System	11 Sep 2020 02:22:09

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '59a45b86-8a9f-4598-b42c-2cc491617a21' User entered 'None (1)'	System	11 Sep 2020 02:22:09
	System	11 Sep 2020 02:22:09

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:07', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '59a45b86-8a9f-4598-b42c-2cc491617a21' User entered '10 Sep 2020 19:22'	System	11 Sep 2020 02:22:09
	System	11 Sep 2020 02:22:09

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 3'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '47b1dc1c-1704-4693-9371-9449ab537f84' User entered 'None (1)'	System	12 Sep 2020 14:57:41
	System	12 Sep 2020 14:57:41

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:32', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '47b1dc1c-1704-4693-9371-9449ab537f84'	System	12 Sep 2020 14:57:41
User entered 'No (N)'	System	12 Sep 2020 14:57:41

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '47b1dc1c-1704-4693-9371-9449ab537f84'	System	12 Sep 2020 14:57:41
User entered 'No (N)'	System	12 Sep 2020 14:57:41

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '47b1dc1c-1704-4693-9371-9449ab537f84' User entered 'None (1)'	System	12 Sep 2020 14:57:41
	System	12 Sep 2020 14:57:41

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:39', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '47b1dc1c-1704-4693-9371-9449ab537f84' User entered '12 Sep 2020 07:57'	System	12 Sep 2020 14:57:41
	System	12 Sep 2020 14:57:41

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 4'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '311e9615-3e99-434d-afa5-667075fd7d06'	System	13 Sep 2020 00:25:52
User entered 'None (1)'	System	13 Sep 2020 00:25:52

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '311e9615-3e99-434d-afa5-667075fd7d06'	System	13 Sep 2020 00:25:52
User entered 'No (N)'	System	13 Sep 2020 00:25:52

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:39', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '311e9615-3e99-434d-afa5-667075fd7d06'	System	13 Sep 2020 00:25:52
User entered 'No (N)'	System	13 Sep 2020 00:25:52

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:43', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '311e9615-3e99-434d-afa5-667075fd7d06'	System	13 Sep 2020 00:25:52
User entered 'None (1)'	System	13 Sep 2020 00:25:52

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:25:49', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '311e9615-3e99-434d-afa5-667075fd7d06' User entered '12 Sep 2020 17:25'	System	13 Sep 2020 00:25:52
	System	13 Sep 2020 00:25:52

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 5'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b77e3f19-70b6-498b-8010-200a950b993e'	System	14 Sep 2020 13:46:01
User entered 'None (1)'	System	14 Sep 2020 13:46:01

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b77e3f19-70b6-498b-8010-200a950b993e' User entered 'No (N)'	System	14 Sep 2020 13:46:01
	System	14 Sep 2020 13:46:01

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:49', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b77e3f19-70b6-498b-8010-200a950b993e' User entered 'No (N)'	System	14 Sep 2020 13:46:01
	System	14 Sep 2020 13:46:01

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b77e3f19-70b6-498b-8010-200a950b993e' User entered 'None (1)'	System	14 Sep 2020 13:46:01
	System	14 Sep 2020 13:46:01

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:45:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b77e3f19-70b6-498b-8010-200a950b993e' User entered '14 Sep 2020 06:45'	System	14 Sep 2020 13:46:01
	System	14 Sep 2020 13:46:01

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 6'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '416c3826-0312-44f5-9bd3-b437badccae1' User entered 'None (1)'	System	15 Sep 2020 14:21:32
	System	15 Sep 2020 14:21:32

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '416c3826-0312-44f5-9bd3-b437badccae1' User entered 'No (N)'	System	15 Sep 2020 14:21:32
	System	15 Sep 2020 14:21:32

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:19', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '416c3826-0312-44f5-9bd3-b437badccae1' User entered 'No (N)'	System	15 Sep 2020 14:21:32
	System	15 Sep 2020 14:21:32

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '416c3826-0312-44f5-9bd3-b437badccae1' User entered 'None (1)'	System	15 Sep 2020 14:21:32
	System	15 Sep 2020 14:21:32

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '416c3826-0312-44f5-9bd3-b437badccae1' User entered '15 Sep 2020 07:21'	System	15 Sep 2020 14:21:32
	System	15 Sep 2020 14:21:32

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 7'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8d57bfa-be9b-491e-a6c9-6af24eb2ec51'	System	16 Sep 2020 01:05:57
User entered 'None (1)'	System	16 Sep 2020 01:05:57

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8d57bfa-be9b-491e-a6c9-6af24eb2ec51' User entered 'No (N)'	System	16 Sep 2020 01:05:57
	System	16 Sep 2020 01:05:57

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8d57bfa-be9b-491e-a6c9-6af24eb2ec51' User entered 'No (N)'	System	16 Sep 2020 01:05:57
	System	16 Sep 2020 01:05:57

US3112210

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:09:52

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 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8d57bfa-be9b-491e-a6c9-6af24eb2ec51' User entered 'None (1)'	System	16 Sep 2020 01:05:57
	System	16 Sep 2020 01:05:57

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:05:55', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8d57bfa-be9b-491e-a6c9-6af24eb2ec51' User entered '15 Sep 2020 18:05'	System	16 Sep 2020 01:05:57
	System	16 Sep 2020 01:05:57

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:11:20



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:18', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:28', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'None (0)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered 'No (N)'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T11:39:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e2586af5-69a1-483c-bb73-ae62c360917d' User entered '09 Sep 2020 11:39'	System	09 Sep 2020 18:39:47
	System	09 Sep 2020 18:39:47



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 11:22'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 13:52'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:21', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'None (0)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered 'No (N)'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-09T20:40:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '5cec1bce-cd8e-47c1-a5e4-c703995d94f3' User entered '09 Sep 2020 20:40'	System	10 Sep 2020 03:40:40
	System	10 Sep 2020 03:40:40

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '09 Sep 2020 14:47'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 2'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:24', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505'	System	11 Sep 2020 02:22:49
User entered 'No interference with activity (1)'	System	11 Sep 2020 02:22:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'None (0)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'None (0)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'None (0)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'None (0)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'None (0)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered 'No (N)'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-10T19:22:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '56f37c8d-794e-4aea-9419-99d1b8488505' User entered '10 Sep 2020 19:22'	System	11 Sep 2020 02:22:49
	System	11 Sep 2020 02:22:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:11:20



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 3'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:54', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:57', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:57:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'None (0)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:58:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered 'No (N)'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T07:58:09', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8998067a-0f55-4405-9d61-69560a32788b' User entered '12 Sep 2020 07:58'	System	12 Sep 2020 14:58:10
	System	12 Sep 2020 14:58:10

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 4'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:20', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:35', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:37', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'None (0)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:42', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered 'No (N)'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-12T17:26:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ee91ba90-cfdd-49f1-b05a-8243854d60b1' User entered '12 Sep 2020 17:26'	System	13 Sep 2020 00:26:49
	System	13 Sep 2020 00:26:49

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 5'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:07', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:10', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:12', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'None (0)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:19', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered 'No (N)'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-14T06:46:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6f0c983b-f515-429e-ba96-9b7a237f8be9' User entered '14 Sep 2020 06:46'	System	14 Sep 2020 13:46:28
	System	14 Sep 2020 13:46:28

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:11:20



**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 6'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:42', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:43', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:45', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'None (0)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:21:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered 'No (N)'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T07:22:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf8092a-2f5c-4dc3-8674-05b6d934824e' User entered '15 Sep 2020 07:22'	System	15 Sep 2020 14:22:04
	System	15 Sep 2020 14:22:04

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	09 Sep 2020 18:11:20
User entered 'Day 7'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:02', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25



US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'None (0)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

US3112210

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:09:52

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered 'No (N)'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-09-15T18:06:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8706d559-1e27-4704-9aaa-76ce75b281b0' User entered '15 Sep 2020 18:06'	System	16 Sep 2020 01:06:25
	System	16 Sep 2020 01:06:25

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:09:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:11:20

**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:29:12



**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:29:12

**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:29:12

**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:29:12

**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:43:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:29:17

**US3112210**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	17 Sep 2020 14:29:17

**US3112210**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:40

**US3112210**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:40

**US3112210**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:40



US3112210

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:40

US3112210

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:24:49

**US3112210**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	23 Sep 2020 21:24:49

**US3112210**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 23:14:41

**US3112210**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '30 Sep 2020'	Karen Mylerberg (b) (4)	30 Sep 2020 23:14:41

**US3112210**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	30 Sep 2020 23:14:41

US3112210

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 23:14:41

**US3112210**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 23:14:48



**US3112210**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	30 Sep 2020 23:14:48

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 16:19:03

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '7 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 16:19:03

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	13 Oct 2020 16:19:03

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'VISIT3'	System	13 Oct 2020 16:19:03

US3112210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '7 Oct 2020'	(b) (4) Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '9:52'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05



**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '7 Oct 2020 9:52'	System	13 Oct 2020 16:21:05

US3112210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '98.1' F	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

US3112210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '66'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'bpm'	System	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '16'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

US3112210

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'breaths/min'	System	13 Oct 2020 16:21:05



**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '131'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '70'	Natalie Moy (b) (4)	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'mmHg'	System	13 Oct 2020 16:21:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45

US3112210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'No (N)'	Natalie Moy (b) (4)	13 Oct 2020 16:21:21

US3112210

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered empty.	(b) (4) Natalie Moy (b) (4)	13 Oct 2020 16:21:21



US3112210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 16:21:57

US3112210

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '7 Oct 2020'	(b) (4) Natalie Moy (b) (4)	13 Oct 2020 16:21:57

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered '10:08'	Natalie Moy (b) (4)	13 Oct 2020 16:21:57

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered '7 Oct 2020 10:08'	System	13 Oct 2020 16:21:57

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:04:37
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 16:22:05

**US3112210**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	13 Oct 2020 16:22:05

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 64'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-12T06:50:19', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6fa7fcd9-0666-41ae-afbc-ca9f0f7e4906'	System	12 Oct 2020 13:50:39
User entered 'No (N)'	System	12 Oct 2020 13:50:39



**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-12T06:50:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6fa7fcd9-0666-41ae-afbc-ca9f0f7e4906'	System	12 Oct 2020 13:50:39
User entered 'No (N)'	System	12 Oct 2020 13:50:39

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-12T06:50:35', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6fa7fcd9-0666-41ae-afbc-ca9f0f7e4906' User entered '12 Oct 2020 06:50:35'	System	12 Oct 2020 13:50:39
	System	12 Oct 2020 13:50:39

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 71'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-19T06:55:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '359bce10-fe8b-4427-95a2-b0e5665ef0eb' User entered 'No (N)'	System	19 Oct 2020 13:55:29
	System	19 Oct 2020 13:55:29

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-19T06:55:12', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '359bce10-fe8b-4427-95a2-b0e5665ef0eb'	System	19 Oct 2020 13:55:29
User entered 'No (N)'	System	19 Oct 2020 13:55:29

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-19T06:55:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '359bce10-fe8b-4427-95a2-b0e5665ef0eb' User entered '19 Oct 2020 06:55:25'	System	19 Oct 2020 13:55:29
	System	19 Oct 2020 13:55:29



**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 78'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-27T09:03:43', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'aec2e19a-e445-4801-8cc6-3e294fdcdc32'	System	27 Oct 2020 16:13:48
User entered 'No (N)'	System	27 Oct 2020 16:13:48

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-27T09:03:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'aec2e19a-e445-4801-8cc6-3e294fdcdc32'	System	27 Oct 2020 16:13:48
User entered 'No (N)'	System	27 Oct 2020 16:13:48

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-10-27T09:03:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'aec2e19a-e445-4801-8cc6-3e294fdcdc32' User entered '27 Oct 2020 09:03:50'	System	27 Oct 2020 16:13:48
	System	27 Oct 2020 16:13:48

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 19:48:34



**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 92'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-09T06:23:24', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e606f03f-4eea-455a-8978-094d1ed3107b' User entered 'No (N)'	System	09 Nov 2020 13:23:37
	System	09 Nov 2020 13:23:37

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-09T06:23:31', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e606f03f-4eea-455a-8978-094d1ed3107b' User entered 'No (N)'	System	09 Nov 2020 13:23:37
	System	09 Nov 2020 13:23:37

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-09T06:23:34', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'e606f03f-4eea-455a-8978-094d1ed3107b' User entered '09 Nov 2020 06:23:34'	System	09 Nov 2020 13:23:37
	System	09 Nov 2020 13:23:37

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered 'Day 99'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-16T06:36:32', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'dfad7306-5ef6-437f-b2ca-d11c6ed3ddb5'	System	16 Nov 2020 14:36:53
User entered 'No (N)'	System	16 Nov 2020 14:36:53



**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-16T06:36:38', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'dfad7306-5ef6-437f-b2ca-d11c6ed3ddb5'	System	16 Nov 2020 14:36:53
User entered 'No (N)'	System	16 Nov 2020 14:36:53

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-16T06:36:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'dfad7306-5ef6-437f-b2ca-d11c6ed3ddb5' User entered '16 Nov 2020 06:36:50'	System	16 Nov 2020 14:36:53
	System	16 Nov 2020 14:36:53

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:01:56
Data entry locked.	System	12 Aug 2020 19:48:34
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 19:48:34

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-23T00:02:04', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf17e9f-f07e-4217-9d01-0b7586819f40'	System	23 Nov 2020 07:02:19
User entered 'No (N)'	System	23 Nov 2020 07:02:19

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-23T00:02:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf17e9f-f07e-4217-9d01-0b7586819f40'	System	23 Nov 2020 07:02:19
User entered 'No (N)'	System	23 Nov 2020 07:02:19

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-23T00:02:17', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'bcf17e9f-f07e-4217-9d01-0b7586819f40' User entered '23 Nov 2020 00:02:17'	System	23 Nov 2020 07:02:19



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-27T02:36:15', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '0cb077fd-035b-40be-b5b4-ae1a91d4db82' User entered 'No (N)'	System	27 Nov 2020 10:36:47
	System	27 Nov 2020 10:36:47

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-27T02:36:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '0cb077fd-035b-40be-b5b4-ae1a91d4db82' User entered 'No (N)'	System	27 Nov 2020 10:36:47
	System	27 Nov 2020 10:36:47

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-11-27T02:36:46', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '0cb077fd-035b-40be-b5b4-ae1a91d4db82' User entered '27 Nov 2020 02:36:46'	System	27 Nov 2020 10:36:47
	System	27 Nov 2020 10:36:47

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-04T07:42:14', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7eabe94b-a3d4-4ff9-bf56-b11b05c733a9' User entered 'No (N)'	System	04 Dec 2020 15:42:26
	System	04 Dec 2020 15:42:26

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-04T07:42:20', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7eabe94b-a3d4-4ff9-bf56-b11b05c733a9' User entered 'No (N)'	System	04 Dec 2020 15:42:26
	System	04 Dec 2020 15:42:26

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-04T07:42:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '7eabe94b-a3d4-4ff9-bf56-b11b05c733a9' User entered '04 Dec 2020 07:42:23'	System	04 Dec 2020 15:42:26
	System	04 Dec 2020 15:42:26

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-12T14:57:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b5386a43-36c1-49ea-ad59-b4e105551519'	System	12 Dec 2020 22:57:30
User entered 'No (N)'	System	12 Dec 2020 22:57:30



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-12T14:57:23', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b5386a43-36c1-49ea-ad59-b4e105551519'	System	12 Dec 2020 22:57:30
User entered 'No (N)'	System	12 Dec 2020 22:57:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-12T14:57:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b5386a43-36c1-49ea-ad59-b4e105551519' User entered '12 Dec 2020 14:57:25'	System	12 Dec 2020 22:57:30
	System	12 Dec 2020 22:57:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-20T12:43:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9f1689c7-ca83-49e3-b8eb-76d861d833bd' User entered 'No (N)'	System	20 Dec 2020 20:44:08
	System	20 Dec 2020 20:44:08

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-20T12:44:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9f1689c7-ca83-49e3-b8eb-76d861d833bd' User entered 'No (N)'	System	20 Dec 2020 20:44:08

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-20T12:44:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9f1689c7-ca83-49e3-b8eb-76d861d833bd' User entered '20 Dec 2020 12:44:03'	System	20 Dec 2020 20:44:08
	System	20 Dec 2020 20:44:08



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-25T06:55:13', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8e06c7d5-f8b7-4033-bfb4-7a8a9f52d6b9' User entered 'No (N)'	System	25 Dec 2020 14:55:24
	System	25 Dec 2020 14:55:24

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-25T06:55:19', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8e06c7d5-f8b7-4033-bfb4-7a8a9f52d6b9' User entered 'No (N)'	System	25 Dec 2020 14:55:24
	System	25 Dec 2020 14:55:24

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2020-12-25T06:55:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '8e06c7d5-f8b7-4033-bfb4-7a8a9f52d6b9' User entered '25 Dec 2020 06:55:22'	System	25 Dec 2020 14:55:24
	System	25 Dec 2020 14:55:24

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-03T12:26:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c945ab96-3ecb-45d4-b9fb-b1e352782206' User entered 'No (N)'	System	03 Jan 2021 20:26:36
	System	03 Jan 2021 20:26:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-03T12:26:29', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c945ab96-3ecb-45d4-b9fb-b1e352782206' User entered 'No (N)'	System	03 Jan 2021 20:26:36
	System	03 Jan 2021 20:26:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-03T12:26:33', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c945ab96-3ecb-45d4-b9fb-b1e352782206' User entered '03 Jan 2021 12:26:33'	System	03 Jan 2021 20:26:36
	System	03 Jan 2021 20:26:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-08T07:21:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4fa0b7af-a500-4203-93dd-f5352a2c8b70'	System	08 Jan 2021 15:21:52
User entered 'No (N)'	System	08 Jan 2021 15:21:52



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-08T07:21:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4fa0b7af-a500-4203-93dd-f5352a2c8b70'	System	08 Jan 2021 15:21:52
User entered 'No (N)'	System	08 Jan 2021 15:21:52

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-08T07:21:47', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4fa0b7af-a500-4203-93dd-f5352a2c8b70' User entered '08 Jan 2021 07:21:47'	System	08 Jan 2021 15:21:52

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-17T12:01:14', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9e6e522d-bbf8-462d-bf05-420b33988220' User entered 'No (N)'	System	17 Jan 2021 20:01:30
	System	17 Jan 2021 20:01:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-17T12:01:21', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9e6e522d-bbf8-462d-bf05-420b33988220' User entered 'No (N)'	System	17 Jan 2021 20:01:30
	System	17 Jan 2021 20:01:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-17T12:01:26', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '9e6e522d-bbf8-462d-bf05-420b33988220' User entered '17 Jan 2021 12:01:26'	System	17 Jan 2021 20:01:30
	System	17 Jan 2021 20:01:30



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:14:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3' User entered 'Yes (Y)'	System	22 Jan 2021 18:15:33
	System	22 Jan 2021 18:15:33

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:14:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3'	System	22 Jan 2021 18:15:33
User entered 'No (N)'	System	22 Jan 2021 18:15:33

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:14:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3' User entered 'No (N)'	System	22 Jan 2021 18:15:33
	System	22 Jan 2021 18:15:33

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:15:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3' User entered 'Yes (Y)'	System	22 Jan 2021 18:15:33
	System	22 Jan 2021 18:15:33

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:15:16', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3'	System	22 Jan 2021 18:15:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 18:15:33



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-22T10:15:22', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ef6c1d81-30c2-4f80-a96c-32b48d92c2d3' User entered '22 Jan 2021 10:15:22'	System	22 Jan 2021 18:15:33
	System	22 Jan 2021 18:15:33

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-29T06:11:50', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '970ddc10-0928-424c-934b-b6c5537f6448'	System	29 Jan 2021 14:12:03
User entered 'No (N)'	System	29 Jan 2021 14:12:03

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-29T06:11:54', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '970ddc10-0928-424c-934b-b6c5537f6448'	System	29 Jan 2021 14:12:03
User entered 'No (N)'	System	29 Jan 2021 14:12:03

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-01-29T06:11:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '970ddc10-0928-424c-934b-b6c5537f6448' User entered '29 Jan 2021 06:11:58'	System	29 Jan 2021 14:12:03
	System	29 Jan 2021 14:12:03

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-07T12:06:43', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6ed2ea8e-b652-44d7-a932-dd193cfcdf9'	System	07 Feb 2021 20:07:36
User entered 'No (N)'	System	07 Feb 2021 20:07:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-07T12:06:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6ed2ea8e-b652-44d7-a932-dd193cfcdf9'	System	07 Feb 2021 20:07:36
User entered 'No (N)'	System	07 Feb 2021 20:07:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-07T12:07:00', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6ed2ea8e-b652-44d7-a932-dd193cfcdf9'	System	07 Feb 2021 20:07:36
User entered '07 Feb 2021 12:07:00'	System	07 Feb 2021 20:07:36

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-12T07:04:58', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8bcbbfd-1519-49d9-a214-a14ccfff56de' User entered 'No (N)'	System	12 Feb 2021 15:09:58
	System	12 Feb 2021 15:09:58

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-12T07:05:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8bcbbfd-1519-49d9-a214-a14ccfff56de' User entered 'No (N)'	System	12 Feb 2021 15:09:58
	System	12 Feb 2021 15:09:58

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-12T07:05:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd8bcbbfd-1519-49d9-a214-a14ccfff56de' User entered '12 Feb 2021 07:05:03'	System	12 Feb 2021 15:09:58
	System	12 Feb 2021 15:09:58

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-19T07:06:41', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ccdaebcb-fd31-4c95-974c-3765582b48d9' User entered 'No (N)'	System	28 Feb 2021 20:03:30
	System	28 Feb 2021 20:03:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-19T07:06:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ccdaebcb-fd31-4c95-974c-3765582b48d9' User entered 'No (N)'	System	28 Feb 2021 20:03:30
	System	28 Feb 2021 20:03:30



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-19T07:06:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'ccdaebcb-fd31-4c95-974c-3765582b48d9' User entered '19 Feb 2021 07:06:53'	System	28 Feb 2021 20:03:30
	System	28 Feb 2021 20:03:30

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-28T12:03:18', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6805e206-4bd1-49c2-bcd0-96db02116faf' User entered 'No (N)'	System	28 Feb 2021 20:03:57
	System	28 Feb 2021 20:03:57

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-28T12:03:21', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6805e206-4bd1-49c2-bcd0-96db02116faf' User entered 'No (N)'	System	28 Feb 2021 20:03:57
	System	28 Feb 2021 20:03:57

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-28T12:03:25', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '6805e206-4bd1-49c2-bcd0-96db02116faf' User entered '28 Feb 2021 12:03:25'	System	28 Feb 2021 20:03:57
	System	28 Feb 2021 20:03:57

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-07T12:03:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c34900b5-4373-4d3e-8d40-57c6b383d11d' User entered 'No (N)'	System	07 Mar 2021 20:03:22
	System	07 Mar 2021 20:03:22

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-07T12:03:11', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c34900b5-4373-4d3e-8d40-57c6b383d11d' User entered 'No (N)'	System	07 Mar 2021 20:03:22
	System	07 Mar 2021 20:03:22

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-07T12:03:14', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'c34900b5-4373-4d3e-8d40-57c6b383d11d' User entered '07 Mar 2021 12:03:14'	System	07 Mar 2021 20:03:22
	System	07 Mar 2021 20:03:22

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-12T07:10:53', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'cc45439c-7bf3-4604-903f-bb5613e56fd5'	System	12 Mar 2021 15:11:07
User entered 'No (N)'	System	12 Mar 2021 15:11:07

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-12T07:10:56', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'cc45439c-7bf3-4604-903f-bb5613e56fd5'	System	12 Mar 2021 15:11:07
User entered 'No (N)'	System	12 Mar 2021 15:11:07

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-12T07:11:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'cc45439c-7bf3-4604-903f-bb5613e56fd5' User entered '12 Mar 2021 07:11:03'	System	12 Mar 2021 15:11:07
	System	12 Mar 2021 15:11:07

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-19T06:59:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '241e6998-ce76-463c-ae03-8023042996d1' User entered 'No (N)'	System	19 Mar 2021 14:00:05
	System	19 Mar 2021 14:00:05

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-19T06:59:55', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '241e6998-ce76-463c-ae03-8023042996d1' User entered 'No (N)'	System	19 Mar 2021 14:00:05
	System	19 Mar 2021 14:00:05



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-19T06:59:59', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '241e6998-ce76-463c-ae03-8023042996d1' User entered '19 Mar 2021 06:59:59'	System	19 Mar 2021 14:00:05
	System	19 Mar 2021 14:00:05

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-26T10:04:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'f3231f92-656c-4871-9368-b07c3ff2e1ac' User entered 'No (N)'	System	26 Mar 2021 17:06:12
	System	26 Mar 2021 17:06:12

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-26T10:04:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'f3231f92-656c-4871-9368-b07c3ff2e1ac'	System	26 Mar 2021 17:06:12
User entered 'No (N)'	System	26 Mar 2021 17:06:12

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-03-26T10:04:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'f3231f92-656c-4871-9368-b07c3ff2e1ac' User entered '26 Mar 2021 10:04:08'	System	26 Mar 2021 17:06:12
	System	26 Mar 2021 17:06:12

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-04T12:27:40', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b0a7140b-6bb0-4afa-9ec3-2e39c95270f2'	System	04 Apr 2021 19:27:50
User entered 'No (N)'	System	04 Apr 2021 19:27:50

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-04T12:27:45', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b0a7140b-6bb0-4afa-9ec3-2e39c95270f2' User entered 'No (N)'	System	04 Apr 2021 19:27:50
	System	04 Apr 2021 19:27:50

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-04T12:27:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'b0a7140b-6bb0-4afa-9ec3-2e39c95270f2' User entered '04 Apr 2021 12:27:48'	System	04 Apr 2021 19:27:50
	System	04 Apr 2021 19:27:50

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-09T05:57:03', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd5c28252-d2f5-4164-a864-de7d8e75759c' User entered 'No (N)'	System	13 Apr 2021 20:25:46
	System	13 Apr 2021 20:25:46

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-09T05:57:09', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd5c28252-d2f5-4164-a864-de7d8e75759c' User entered 'No (N)'	System	13 Apr 2021 20:25:46
	System	13 Apr 2021 20:25:46

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-09T05:57:12', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'd5c28252-d2f5-4164-a864-de7d8e75759c' User entered '09 Apr 2021 05:57:12'	System	13 Apr 2021 20:25:46
	System	13 Apr 2021 20:25:46

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-16T06:54:01', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4a865111-100f-4bd0-9972-37bc5f59f14' User entered 'No (N)'	System	16 Apr 2021 13:54:13
	System	16 Apr 2021 13:54:13

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-16T06:54:05', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4a865111-100f-4bd0-9972-37bc5f59f14' User entered 'No (N)'	System	16 Apr 2021 13:54:13
	System	16 Apr 2021 13:54:13



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-16T06:54:08', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '4a865111-100f-4bd0-9972-37bcb5f59f14' User entered '16 Apr 2021 06:54:08'	System	16 Apr 2021 13:54:13
	System	16 Apr 2021 13:54:13

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-23T05:12:44', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'baef169c-9e14-4022-aace-558cf459b83d'	System	28 Apr 2021 23:42:37
User entered 'No (N)'	System	28 Apr 2021 23:42:37

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-23T05:12:48', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'baef169c-9e14-4022-aace-558cf459b83d' User entered 'No (N)'	System	28 Apr 2021 23:42:37

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-04-23T05:12:52', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: 'baef169c-9e14-4022-aace-558cf459b83d' User entered '23 Apr 2021 05:12:52'	System	28 Apr 2021 23:42:37
	System	28 Apr 2021 23:42:37

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:19:43



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:19:43

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:19:43



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:19:43



**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:19:43

**US3112210**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:09:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:43
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:19:43



US3112210

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:09:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:27:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-28T12:03:36', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '060e50c5-6e28-4944-892c-86d946cb740f'	System	28 Feb 2021 20:04:12
User entered 'No (N)'	System	28 Feb 2021 20:04:12

**US3112210**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:27:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (520ED511-C97B-4D2A-8293-F742E395424F)', Time: '2021-02-28T12:03:39', User OID: 'PatientReportedOutcome (US3112210)', ODM File OID: '060e50c5-6e28-4944-892c-86d946cb740f' User entered '28 Feb 2021 12:03:39'	System	28 Feb 2021 20:04:12
	System	28 Feb 2021 20:04:12

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:50:31
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	04 Nov 2020 18:58:39

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:50:31
User entered '04 Nov 2020'	(b) (4) Matthew Musikanth (b) (4)	04 Nov 2020 18:58:39

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:50:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Musikanth (b) (4)	04 Nov 2020 18:58:39

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:50:31
User entered empty.	(b) (4) Matthew Musikanth	04 Nov 2020 18:58:39
	(b) (4)	

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:50:31
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	04 Nov 2020 18:58:43
	(b) (4)	

**US3112210**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:19:45
User entered 'I'	System	04 Nov 2020 18:58:43



**US3112210**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Dec 2020 21:47:41

**US3112210**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '8 Dec 2020'	Karen Mylerberg (b) (4) (b) (4)	08 Dec 2020 21:47:41

**US3112210**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	08 Dec 2020 21:47:41

US3112210

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Dec 2020 21:47:41

US3112210

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Dec 2020 21:47:52

**US3112210**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'I'	System	08 Dec 2020 21:47:52

**US3112210**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	07 Jan 2021 23:40:56

**US3112210**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '7 Jan 2021'	Brenda Grande (b) (4) (b) (4)	07 Jan 2021 23:40:56



**US3112210**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	07 Jan 2021 23:40:56

US3112210

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	07 Jan 2021 23:40:56

US3112210

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	07 Jan 2021 23:41:00

**US3112210**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'I'	System	07 Jan 2021 23:41:00

**US3112210**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:07:57

**US3112210**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '8 Feb 2021'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:07:57

**US3112210**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:07:57

US3112210

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:07:57



US3112210

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	15 Feb 2021 18:28:35

**US3112210**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'I'	System	15 Feb 2021 18:28:35

US3112210

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:07

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '24 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:07

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:07

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'VISIT4'	System	24 Mar 2021 21:12:07

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '24 Feb 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02



**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '09:39'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered '24 Feb 2021 09:39'	System	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '98.3' F	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '74'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'bpm'	System	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '16'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02



US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'breaths/min'	System	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '127'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'mmHg'	System	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '74'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 20:49:02

US3112210

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'mmHg'	System	30 Mar 2021 20:49:02

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:09:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24

US3112210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:21



US3112210

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '24 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:21

US3112210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:55

US3112210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '24 Feb 2021'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:55

US3112210

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '10:11'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:12:55

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered '24 Feb 2021 10:11'	System	24 Mar 2021 21:12:55

US3112210

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	24 Mar 2021 21:13:05

**US3112210**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:37:24
User entered 'I'	System	24 Mar 2021 21:13:05

**US3112210**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:53:25



**US3112210**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered '7 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 22:53:25

**US3112210**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Apr 2021 22:53:25

US3112210

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:53:25

US3112210

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:54:20

**US3112210**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:56
User entered 'I'	System	08 Apr 2021 22:54:20

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:37
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:10:37
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[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 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:37
	(b) (4)	



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 16:10:37

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:09:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '6 Jan 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[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 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:24:22

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:24:22

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:09:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:09:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:10:52
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '1'	System	25 Feb 2021 16:10:52

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'I'	System	25 Feb 2021 16:10:52

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered empty.	System	25 Feb 2021 16:11:56
DataPoint set to visible.	System	25 Feb 2021 16:10:52

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered empty.	System	25 Feb 2021 16:11:56
DataPoint set to visible.	System	25 Feb 2021 16:10:52

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '09:39'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '24 Feb 2021 09:39'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '98.3' F	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	



US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '74'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'bpm'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '16'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'breaths/min'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '127'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'mmHg'	System	25 Feb 2021 16:11:56



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '74'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'mmHg'	System	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:09:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered empty.	System	25 Feb 2021 16:11:56
DataPoint set to visible.	System	25 Feb 2021 16:10:52

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '10:56'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '24 Feb 2021 10:56'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '98.2' F	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '70'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'bpm'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '16'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56



US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'breaths/min'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '120'	Natalie Moy (b) (4)	25 Feb 2021 16:11:56
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'mmHg'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Feb 2021 16:12:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	25 Feb 2021 16:12:02
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	25 Feb 2021 16:12:02
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 16:12:02
User entered '74' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:12:02
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Feb 2021 16:11:56
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	25 Feb 2021 16:11:56
User entered '740'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:11:56

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'mmHg'	System	25 Feb 2021 16:11:56

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:12:21
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:12:21
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:12:49



US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Natalie Moy (b) (4) (b) (4)	25 Feb 2021 16:12:49

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	25 Feb 2021 16:12:49
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'mRNA-1273'	System	25 Feb 2021 16:12:49
DataPoint set to visible.	System	25 Feb 2021 16:10:52

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:12:49
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '10:25'	Natalie Moy (b) (4)	25 Feb 2021 16:12:49
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '24 Feb 2021 10:25'	System	25 Feb 2021 16:12:49

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4)	25 Feb 2021 16:12:49
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'ONCE'	System	25 Feb 2021 16:12:49



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:12:49

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:12:59
	(b) (4)	

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:12:59
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '10:11'	Natalie Moy (b) (4)	25 Feb 2021 16:12:59
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '24 Feb 2021 10:11'	System	25 Feb 2021 16:12:59

US3112210

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:13:06
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '24 Feb 2021'	Natalie Moy (b) (4)	25 Feb 2021 16:13:06
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:09:52**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '10:08'	Natalie Moy (b) (4)	25 Feb 2021 16:13:06
	(b) (4)	



**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:09:52**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered '24 Feb 2021 10:08'	System	25 Feb 2021 16:13:06

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	25 Feb 2021 16:13:09
	(b) (4)	

**US3112210**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:54:20
User entered 'I'	System	25 Feb 2021 16:13:09

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	03 Mar 2021 19:31:45
	(b) (4)	

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '3 Mar 2021'	Brenda Grande (b) (4)	03 Mar 2021 19:31:45
	(b) (4)	

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	03 Mar 2021 19:31:45
	(b) (4)	

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	03 Mar 2021 19:31:45
	(b) (4)	

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	03 Mar 2021 19:31:35
	(b) (4)	



**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User entered 'I'	System	03 Mar 2021 19:31:35

**US3112210**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:14:16
User entered 'I'	System	03 Mar 2021 19:31:35
DataPoint set to visible.	System	03 Mar 2021 19:31:35

**US3112210**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:06:51

**US3112210**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '23 Mar 2021'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:06:51

**US3112210**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:06:51

**US3112210**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:09:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'OLD29'	System	23 Mar 2021 22:06:51

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01



**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '23 Mar 2021'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '09:21'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered '23 Mar 2021 09:21'	System	23 Mar 2021 22:08:01

US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '98.2' F	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '68'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'bpm'	System	23 Mar 2021 22:08:01



**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '16'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'breaths/min'	System	23 Mar 2021 22:08:01

US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '121'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'mmHg'	System	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '78'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'mmHg'	System	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01



**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '23 Mar 2021'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '10:28'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered '23 Mar 2021 10:28'	System	23 Mar 2021 22:08:01

US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '98.8' F	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '72'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'bpm'	System	23 Mar 2021 22:08:01



US3112210

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:52

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '16'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'breaths/min'	System	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '112'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'mmHg'	System	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '72'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'mmHg'	System	23 Mar 2021 22:08:01

**US3112210**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:09:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:15

**US3112210**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:09:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '23 Mar 2021'	Brenda Grande (b) (4)	23 Mar 2021 22:08:15
	(b) (4)	



**US3112210**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:31

US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:31

US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:31

**US3112210**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'mRNA-1273'	System	23 Mar 2021 22:08:31
DataPoint set to visible.	System	03 Mar 2021 19:31:35

US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '23 Mar 2021'	Brenda Grande (b) (4)	23 Mar 2021 22:08:31
	(b) (4)	

US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '09:57'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:31

**US3112210**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered '23 Mar 2021 09:57'	System	23 Mar 2021 22:08:31

US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Brenda Grande (b) (4)	23 Mar 2021 22:08:31
	(b) (4)	



US3112210

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'ONCE'	System	23 Mar 2021 22:08:31

**US3112210**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:09:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'INTRAMUSCULAR'	System	23 Mar 2021 22:08:31

US3112210

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 22:08:36

**US3112210**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:37:01
User entered 'I'	System	23 Mar 2021 22:08:36

**US3112210**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:22:58

**US3112210**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '30 Mar 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:22:58

**US3112210**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:22:58

**US3112210**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:09:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:22:58



US3112210

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:22:47

**US3112210**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:09:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 22:22:47

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:09:52**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:06:21
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Jan 2021 20:59:05

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:47
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:00:40
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:00:32
User entered 'USA-US062-2021-mRNA-1273-P301000007'	(b) (4), (b) (6)	11 Feb 2021 15:00:32
reason for change: Per Query Resolution		
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:59:48
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 20:55:19
DataPoint Un-verified.	(b) (4), (b) (6)	10 Feb 2021 20:55:19
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Feb 2021 20:55:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:03
User entered	System	25 Jan 2021 14:31:45
'USA-US062-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 14:31:45

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Endometrial neoplasms malignant, PT: Endometrial cancer, LLT: Endometrial cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 21:02:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 21:02:17
Data point term sent to Coder	System	22 Jan 2021 21:00:57
User entered 'Endometrial Cancer'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09



**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '11 Jan 2021'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 21:00:09

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:29
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:15:49
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:49
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:49
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:32
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:50:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:16:26
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Feb 2021 17:16:26
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. Please leave query open until information is available. ' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:54
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:34
User entered '27 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:34
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 22:01:49
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:05:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

If not Ongoing, end date (dd MMM yyyy)

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.' answered with 'awaiting medical record will update once they are received ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 22:09:04
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 15:40:23
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 21:00:09



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:41
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	10 Feb 2021 22:34:19
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:34
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Grade 4 (Grade 4)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:49:18
User closed query 'PV Urgent Query: Please confirm if the event is in fact non-serious or if it meets medically significant serious criteria. If it meets medically significant criteria, please update event back to SAE.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:43:57
Query 'PV Urgent Query: Please confirm if the event is in fact non-serious or if it meets medically significant serious criteria. If it meets medically significant criteria, please update event back to SAE.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4)	10 Feb 2021 22:34:51
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 22:34:40
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 22:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	10 Feb 2021 22:34:19
	(b) (4)	
User opened query 'PV Urgent Query: Please confirm if the event is in fact non-serious or if it meets medically significant serious criteria. If it meets medically significant criteria, please update event back to SAE.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 21:47:33
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:16:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 17:16:35
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Feb 2021 17:16:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:16:26
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Feb 2021 17:16:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Brenda Grande (b) (4)	09 Feb 2021 17:16:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4)	09 Feb 2021 17:16:26
	(b) (4)	
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Yes (Y)'	Matthew Musikanth	22 Jan 2021 21:00:09
	(b) (4)	

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:53:07
User entered '0' reason for change: Data Entry Error	Matthew Musikanth	18 Feb 2021 16:59:46
	(b) (4)	
User closed query 'PV Query: Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this event. Should serious criterion be considered Medically Significant instead? If it is to remain life threatening, please clarify.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 17:08:05
Query 'PV Query: Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this event. Should serious criterion be considered Medically Significant instead? If it is to remain life threatening, please clarify.' answered with 'per-pi endometrial cancer is considered life threatening ' (Site from Safety).	Brenda Grande (b) (4)	16 Feb 2021 17:20:32
	(b) (4)	
User opened query 'PV Query: Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this event. Should serious criterion be considered Medically Significant instead? If it is to remain life threatening, please clarify.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 12:51:01
User entered '1' reason for change: Data Entry Error	Brenda Grande (b) (4)	10 Feb 2021 22:34:40
	(b) (4)	

US3112210

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Life threatening was reported as a serious criterion for the event of "endometrial cancer" Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this case.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:49:54
Query 'PV Query: Life threatening was reported as a serious criterion for the event of "endometrial cancer" Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this case.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4)	09 Feb 2021 17:16:42
DataPoint Un-verified.	(b) (4)	09 Feb 2021 17:15:34
User entered '0' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Feb 2021 17:15:34
User opened query 'PV Query: Life threatening was reported as a serious criterion for the event of "endometrial cancer" Life threatening criteria is applicable if the patient was in an imminent situation where lifesaving treatment or interventions were necessary to save their life. As this event was not immediately life-threatening, please update the serious criterion for this case.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:41:55
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '1'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09



**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:53:11
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Feb 2021 16:59:46
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Medications taken for operation as treatment for endometrial cancer, conmeds updated to clarify. However indication is not verbatim as medication was not taken as a direct treatment of the AE. ' (Site from DM).	(b) (4), (b) (6) Matthew Musikanth (b) (4)	16 Mar 2021 19:13:09 16 Mar 2021 17:15:22
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 23:35:31 19 Feb 2021 00:46:10
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:29:15
User entered '1' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:29:15
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered '0'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'I'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:50:36
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:49:20
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:16:48
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:16:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:16:26
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:40:32
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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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) (b) (4)	19 Mar 2021 20:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:05
	(b) (4)	
User closed query 'Per DM CLR: Narrative = BILATERAL SALPINGO OOPHORECTOMY WITH STAGE, BILATERAL PELVIC LYMPH NODE DISSECTION BILATERAL URETROLYSIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:14:01
User closed query 'Per DM CLR: Narrative = LEFT SPINE MRI ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:13:40
User closed query 'Per DM CLR: Narrative = UTERINE BIOPSY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:13:37
User closed query 'Per DM CLR: Narrative = ABDOMEN CT ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:13:33
User closed query 'Per DM CLR: Narrative = CXR ON THE 22JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:13:26
User closed query 'Per DM CLR: Narrative = PT. SEEN AT PCP FOR DIAGNOSTICS. Please review and confirm what are these "DIAGNOSTICS" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 19:13:24
Query 'Per DM CLR: Narrative = UTERINE BIOPSY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'previous Data management directive to not report diagnostics in conprocedure page. Please Advise. ' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:10:45

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = LEFT SPINE MRI ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'previous Data management directive to not report diagnostics in conprocedure page. Please Advise. ' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:10:42
Query 'Per DM CLR: Narrative = ABDOMEN CT ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'previous Data management directive to not report diagnostics in conprocedure page. Please Advise. ' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:10:40
Query 'Per DM CLR: Narrative = CXR ON THE 22JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'previous Data management directive to not report diagnostics in conprocedure page. Please Advise. ' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:10:37
Query 'Per DM CLR: Narrative = PT. SEEN AT PCP FOR DIAGNOSTICS. Please review and confirm what are these "DIAGNOSTICS" and ensure that this is captured in the appropriate eCRF. ' answered with 'Routine diagnostics for age, previous Data management directive to not report diagnostics in conprocedure page. Please Advise. ' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:10:31
Query 'Per DM CLR: Narrative = BILATERAL SALPINGO OOPHORECTOMY WITH STAGE, BILATERAL PELVIC LYMPH NODE DISSECTION BILATERAL URETROLYSIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated, previous existing term "Total Hysterectomy"' (Site from DM).	Matthew Musikanth (b) (4)	16 Mar 2021 17:09:25



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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = BILATERAL SALPINGO OOPHORECTOMY WITH STAGE, BILATERAL PELVIC LYMPH NODE DISSECTION BILATERAL URETROLYSIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:35:24
User opened query 'Per DM CLR: Narrative = UTERINE BIOPSY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:35:17
User opened query 'Per DM CLR: Narrative = LEFT SPINE MRI ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:35:12
User opened query 'Per DM CLR: Narrative = ABDOMEN CT ON THE 20JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:35:07
User opened query 'Per DM CLR: Narrative = CXR ON THE 22JAN2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:35:01
User opened query 'Per DM CLR: Narrative = PT. SEEN AT PCP FOR DIAGNOSTICS. Please review and confirm what are these "DIAGNOSTICS" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:34:56
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:34:11
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 16:38:52

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' answered with 'updated thank you' (Site from Safety).	Natalie Moy (b) (4)	26 Feb 2021 17:21:32
DataPoint Un-verified.	(b) (4)	
	Natalie Moy (b) (4)	26 Feb 2021 17:20:59
	(b) (4)	
User entered 'PT. SEEN AT PCP FOR DIAGNOSTICS AND WAS RECENTLY DIAGNOSED WITH ENDOMETRIAL CANCER. SUBJECT HAS HAD A HYSTERECTOMY DONE ON 27JAN2021.	Natalie Moy (b) (4)	26 Feb 2021 17:20:59
	(b) (4)	
subject had a physical exam, and a CXR on the 22Jan2021. They had an abdomen CT on the 20Jan2021. They had a left spine MRI on the 20Jan2021. endometrial cancer determined by uterine biopsy. Planned procedure for total laparoscopic hysterectomy bilateral salpingo oophorectomy with stage, bilateral pelvic lymph node dissection bilateral uretrolysis.' reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:50:34
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide date and details of hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 17:08:11
Query 'PV Query: Please provide date and details of hysterectomy.' answered with 'updated ' (Site from Safety).	Brenda Grande (b) (4)	16 Feb 2021 17:23:06
	(b) (4)	
DataPoint Un-verified.	Brenda Grande (b) (4)	16 Feb 2021 17:23:01
	(b) (4)	
User entered 'PT. SEEN AT PCP FOR DIAGNOSTICS AND WAS RECENTLY DIAGNOSED WITH ENDOMETRIAL CANCER. SUBJECT HAS HAD A HYSTERECTOMY DONE ON 27JAN2021.' reason for change: Data Entry Error	Brenda Grande (b) (4)	16 Feb 2021 17:23:01
	(b) (4)	
User opened query 'PV Query: Please provide date and details of hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 12:50:38

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 12:50:29
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:50:07
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 17:49:35
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)	10 Feb 2021 17:49:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' answered with 'awaiting medical records' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:37:38
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 'updated ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:29:59
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:20:31

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, used to diagnose and or monitor the event, with dates performed. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:42:05
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 15:41:32
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 15:40:40
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:04
User entered 'PT. SEEN AT PCP FOR DIAGNOSTICS AND WAS RECENTLY DIAGNOSED WITH ENDOMETRIAL CANCER. Scheduled for complete hysterectomy.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Jan 2021 21:01:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 21:00:43
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Jan 2021 21:00:43
User entered 'Pt. seen at PCP for diagnostics and was recently diagnosed with endometrial cancer.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:43
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Jan 2021 21:00:09
User entered empty.	Matthew Musikanth (b) (4)	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 22:34:19
User entered '0'	System	09 Feb 2021 17:16:35
User entered '1'	System	22 Jan 2021 21:00:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Jan 2021 21:00:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 23:02:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 23:02:51
Data point term sent to Coder	System	08 Apr 2021 23:01:41
User entered 'Basal cell carcinoma'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '19 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 23:00:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 23:00:55



**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55



**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Apr 2021 23:00:55



**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

US3112210

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6) (b) (4)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:07:46
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 23:00:55

**US3112210**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 23:00:55



US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:09:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:51:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:30:18
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 23:51:36

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 21:32:44
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	23 Sep 2020 21:32:44
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	23 Sep 2020 21:32:06
User entered 'Advil'	Karen Mylerberg (b) (4)	23 Sep 2020 21:31:28
	(b) (4)	

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:21:44
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'does not meet reporting criteria for AE' (Site from DM).	Natalie Moy (b) (4) (b) (4)	21 Oct 2020 17:20:41
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:58:15
User entered 'headache'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '440'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'once (ONCE)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28



US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '13 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '13 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28

US3112210

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	23 Sep 2020 21:31:28



**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:31:28

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:31:28

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:48:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:48:33
Data point term sent to Coder	System	09 Feb 2021 17:32:32
User entered 'flu vaccine'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'influenza prophylaxis'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '0.5'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'mL (mL)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31



**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'once (ONCE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:52

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '29 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31



**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered '29 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User entered empty.	System	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User entered empty.	System	09 Feb 2021 17:32:31

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:40
User entered empty.	System	09 Feb 2021 17:32:31

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:58:47
Data point term sent to Coder	System	16 Mar 2021 17:13:06
Coding entries removed.	Matthew Musikanth	16 Mar 2021 17:12:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 23:53:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 22:20:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 22:20:37
Data point term sent to Coder	System	09 Feb 2021 17:34:33
User entered 'gabapentin'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Un-verified.	Matthew Musikanth (b) (4)	16 Mar 2021 17:12:58
User entered 'PRE AND POST OPERATIVE PAIN RELIEF (ENDOMETRIAL CANCER Treatment)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Mar 2021 17:12:58
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'pre and post operative pain relief'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01



US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered '300'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'mg (mg)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'once daily (QD)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'Oral (ORAL)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered '26 Jan 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01



**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered '03 Feb 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:15
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User entered '1'	System	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User entered '1'	System	09 Feb 2021 17:34:01

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:44
User entered '804 (804)'	System	09 Feb 2021 17:34:01

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:24:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:24:40
Data point term sent to Coder	System	16 Mar 2021 17:14:07
Coding entries removed.	Matthew Musikanth	16 Mar 2021 17:13:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 23:53:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 12:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 12:03:51
Data point term sent to Coder	System	09 Feb 2021 17:35:34
User entered 'docusate sodium'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18



US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Un-verified.	Matthew Musikanth (b) (4)	16 Mar 2021 17:13:11
User entered 'STOOL SOFTENER POST OP (ENDOMETRIAL CANCER treatment)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Mar 2021 17:13:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'stool softener post op'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered '200'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'mg (mg)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'once daily (QD)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'Oral (ORAL)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18



US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered '28 Jan 2021'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 10:02:44
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:42:35
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:40:11
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:40:11
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 07:22:31
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:40:11
User entered '3 Feb 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 22:40:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:53:19
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User entered '1'	System	09 Feb 2021 17:35:18

**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User entered '1'	System	09 Feb 2021 17:35:18



**US3112210**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:20:49
User entered '804 (804)'	System	09 Feb 2021 17:35:18

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:09:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:47:44
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:09:07

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:02
User entered '27 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:09:59

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Un-verified.	Matthew Musikanth	16 Mar 2021 17:05:22
	(b) (4)	
User entered 'LAPAROSCOPIC HYSTERECTOMY BILATERAL SALPINGO OOPHORECTOMY WITH STAGE, BILATERAL PELVIC LYMPH NODE DISSECTION BILATERAL URETROLYSIS.' reason for change: Data Entry Error	Matthew Musikanth	16 Mar 2021 17:05:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:02
	(b) (4)	
User entered 'total hysterectomy'	Brenda Grande (b) (4)	08 Feb 2021 21:09:59
	(b) (4)	

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:09:22
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 06:32:39
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	01 Mar 2021 16:11:04
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 16:09:44
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	01 Mar 2021 16:08:45
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 16:08:45
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 16:08:45
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:29:36
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:02
User entered 'Other (OTHER)'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:09:59

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:09:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:09:24
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 16:11:04
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 16:11:04
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:48:02
User entered 'endometrial cancer'	Brenda Grande (b) (4) (b) (4)	08 Feb 2021 21:09:59

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:52

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	08 Apr 2021 23:04:24

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered 'Excisional biopsy'	(b) (4), (b) (6)	08 Apr 2021 23:04:24



US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	08 Apr 2021 23:04:24

US3112210

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:09:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:07:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:04:24

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered '25/Jan/2021 14:33'	System	25 Jan 2021 14:33:08

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '10/Feb/2021 12:50'	System	10 Feb 2021 17:50:59

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 17:50:59

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '11/Feb/2021 10:28'	System	11 Feb 2021 15:28:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:07:14
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 15:28:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '17/Feb/2021 12:10'	System	17 Feb 2021 17:10:21

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 17:10:21

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '18/Feb/2021 15:57'	System	18 Feb 2021 20:57:31

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 20:57:31

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'USA-US062-2021-MRNA-1273-P301000007'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:27
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
User entered 'No (N)'	System	18 Feb 2021 16:59:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:28:16
Un-reviewed for Safety.	System	11 Feb 2021 15:00:32
User entered 'Yes (Y)'	System	11 Feb 2021 15:00:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
Un-reviewed for Safety.	System	09 Feb 2021 17:15:34
DataPoint Un-verified.	System	09 Feb 2021 17:15:34
User entered 'No (N)'	System	09 Feb 2021 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Yes (Y)'	System	25 Jan 2021 14:31:45



**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 16:39:01
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:51:25
Un-reviewed for Safety.	System	18 Feb 2021 16:59:46
DataPoint Un-verified.	System	18 Feb 2021 16:59:46
User entered 'Yes (Y)'	System	18 Feb 2021 16:59:46
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'No (N)'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Laurie'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'Han-Conrad'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '9040 Friars Rd St 540'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'San Diego'	System	25 Jan 2021 14:31:45



US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered 'CA'	System	25 Jan 2021 14:31:45

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:32:58
User entered '92108'	System	25 Jan 2021 14:31:45

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:52

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 17:50:45
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 23:08:17
User entered 'US'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:09:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	01 Mar 2021 16:39:10
User entered '5'	System	18 Feb 2021 20:57:31
User entered '4'	System	17 Feb 2021 17:10:21
User entered '3'	System	11 Feb 2021 15:28:45
User entered '2'	System	10 Feb 2021 17:50:59
User entered '1'	System	25 Jan 2021 14:33:08

**US3112210**

**Folder: SAE USA-US062-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:09:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:15:05
	(b) (4)	
User entered '01/Mar/2021 11:39'	System	01 Mar 2021 16:39:10

US3112210

Folder: SAE USA-US062-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:09:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:15:05
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 16:39:10