

US3412200 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:31:09

All time stamps listed in this document are displayed in GMT

US3412200

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

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Participant ID

US3412200

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

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US3412200

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3412200

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	31
Age Units	YEARS
Age (Derived)	31
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) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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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) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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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) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Condition	SEASONAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	9:56 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 9:56
Height ( <i>xxx.x</i> )	161.5 cm
Weight ( <i>xxx.x</i> )	69.9 kg
BMI ( <i>xxx.x</i> )	26.79984 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) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

11 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) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Date of assessment (dd MMM yyyy) 11 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) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 11 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3412200

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

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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**

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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) 13 Feb 2021 04:56:59

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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>	



US3412200

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 102609

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

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)	11 AUG 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:56
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

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)	11 AUG 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:05
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

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: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 11 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3412200

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 11:25

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	11 AUG 2020 10:40

US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:17	11 AUG 2020 10:17
Nasopharyngeal Swab 2	No		

US3412200

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**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

11 AUG 2020 12:10

PC Open Date & Time

11 AUG 2020 11:45

PC Close Date & Time

11 AUG 2020 14:15

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**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 98.7 °F

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

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

PC Time Stamp	11 AUG 2020 18:46
PC Open Date & Time	11 AUG 2020 15:10
PC Close Date & Time	12 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 16:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**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

98.0 °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

13 AUG 2020 21:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 22:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**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

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

16 AUG 2020 19:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**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

98.5 °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

17 AUG 2020 19:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☒

No ☐

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

17

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:13

PC Open Date & Time

11 AUG 2020 11:45

PC Close Date & Time

11 AUG 2020 14:15

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

25

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:53

PC Open Date & Time

11 AUG 2020 15:10

PC Close Date & Time

12 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**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

12 AUG 2020 16:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**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

13 AUG 2020 21:08

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**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

14 AUG 2020 22:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**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

16 AUG 2020 19:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**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

17 AUG 2020 19:18

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:14
PC Open Date & Time	11 AUG 2020 11:45
PC Close Date & Time	11 AUG 2020 14:15

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:53
PC Open Date & Time	11 AUG 2020 15:10
PC Close Date & Time	12 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**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 ☒



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 16:42
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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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US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:09
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**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

51 of 2163

EAB) (1725)

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**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  
EAB) (1725)

53 of 2163

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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 ☒

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EAB) (1725)



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:10
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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 ☐

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp 19 AUG 2020 05:13

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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

PC Time Stamp

20 AUG 2020 05:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 19 AUG 2020 05:13

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

20 AUG 2020 05:14

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 AUG 2020 05:13

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59



US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:09

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 05:13
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:09

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 05:15
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

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)	8 SEP 2020
Time of assessment (00:00-23:59)	07:24 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 07:24
Temperature (xxx.x)	36.9 C
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)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

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)	8 SEP 2020
Time of assessment (00:00-23:59)	9:21 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 9:21
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3412200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	8 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3412200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 08:50

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

US3412200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	8:12 (24 HR)
Collection date and time (derived)	8 SEP 2020 8:12

US3412200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:18	8 SEP 2020 08:18
Nasopharyngeal Swab 2	No		



US3412200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**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

98.1 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 08 SEP 2020 09:27

PC Open Date & Time 08 SEP 2020 09:10

PC Close Date & Time 08 SEP 2020 11:40

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**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 98.7 °F

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

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

PC Time Stamp	08 SEP 2020 16:59
PC Open Date & Time	08 SEP 2020 12:35
PC Close Date & Time	09 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °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

09 SEP 2020 18:33

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:54

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**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 ☒

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 11 SEP 2020 20:59

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 09:35

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**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

08 SEP 2020 09:28

PC Open Date & Time

08 SEP 2020 09:10

PC Close Date & Time

08 SEP 2020 11:40

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

40

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

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

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

08 SEP 2020 17:00

PC Open Date & Time

08 SEP 2020 12:35

PC Close Date & Time

09 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:03

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**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

11 SEP 2020 20:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

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

60

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

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

Yes ☐

No ☒

Please record - **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 SEP 2020 09:37

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:28
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PC Open Date & Time	08 SEP 2020 09:10
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PC Close Date & Time	08 SEP 2020 11:40
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US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**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 ☐

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:00
PC Open Date & Time	08 SEP 2020 12:35
PC Close Date & Time	09 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**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 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:03
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 09:38
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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)

111 of 2163



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:56:59

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

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*

US3412200

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:45:30

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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



US3412200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3412200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

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.*

US3412200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 OCT 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

06 OCT 2020 15:20

US3412200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:45:31

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3412200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59



US3412200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3412200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 09:30:27
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3412200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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	15 NOV 2020 04:03:42
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 05:42:18

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 14:33:17
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

06 DEC 2020 10:01:58

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

11 DEC 2020 19:29:14

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

19 DEC 2020 15:43:49

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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24 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

---

28 DEC 2020 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

18 JAN 2021 09:41:57

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 04:33:41

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

28 JAN 2021 05:02:14

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 09:21:35
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 04:29:19

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

25 FEB 2021 20:18:27

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

04 MAR 2021 16:46:00

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 215

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

18 MAR 2021 12:30:38

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 MAR 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAR 2021 23:59
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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

01 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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

17 APR 2021 16:32:47

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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22 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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21 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 OCT 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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07 FEB 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 FEB 2022 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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 <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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	02 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2022 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59



US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

**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 ☐

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3412200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:09

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"/>

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

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[Patient Cloud Close Date & Time](#)

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17 OCT 2022 23:59

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US3412200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:31:09

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
Yes	Yes	04 MAR 2021 16:46:29

US3412200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:35:50

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3412200

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:35:50

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3412200

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

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

Comments  
*If Contact Not Made, please provide Comments*

CALLED BUT VOICE MAIL BOX  
WAS FULL, COULD NOT REACH  
ON 5 FEB 2021, 8 FEB 2021, OR 9  
FEB 2021

US3412200

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

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	VISIT4
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US3412200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:39:44

Generated On: 09 Jun 2021 17:31:09

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3412200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

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.*

US3412200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

10:46 (24 HR)

Collection date and time (derived)

23 MAR 2021 10:46

US3412200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED AND PATIENT HAD A  
FULL MAILBOX ON 06 APR 2021.

*If Contact Not Made, please provide Comments*

**US3412200**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3412200**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:31:09**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

**US3412200**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:31:09**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3412200

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

---

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

---

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

---

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

---

Folder OID	UNBLND_DECIDE
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US3412200

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3412200

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	18 JAN 2021 11:18

US3412200

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:39:43

Generated On: 09 Jun 2021 17:31:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	11:17
Collection Date and Time (derived)	18 JAN 2021 11:17

US3412200

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:35:01

Generated On: 09 Jun 2021 17:31:09

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

AEID	
Adverse event	WORSENING DEPRESSION
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)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

---

SUBJECT REPORTED A  
WORSENING OF DEPRESSION  
~20SEP2020. SUBJECT WAS  
STARTED ON REMERON 7.5MG  
PER PSYCHIATRIST &  
INCREASED TO 15MG ON  
02FEB2021 DUE TO PERSISTENT  
SYMPTOMS. SUBJECT REPORTS  
IMPROVEMENT IN DEPRESSED  
MOOD SINCE START OF  
REMERON. DENIES SUICIDAL  
IDEATION/INTENTION.

---

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)	

---



US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

AEID	USA-US061-2021-MRNA-1273-P30 1000018
Adverse event	SEVERE DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

---

SUBJECT NOTIFIED OUR SITE  
AT 3:45 PM ON 14-APR-2021 OF  
HER HOSPITALIZATION ON  
060APR-2021 TO 14-APR-2021  
FOR SEVER DEPRESSION AND  
PTSD. SUBJECT WAS  
PRESCRIBED CONMED  
ZYPREXA 5MG TO START AS  
NEEDED ON 06-APR-2021.  
SUBJECT WILL START DAILY  
OUT PATIENT THERAPY ON  
15-APR-2021

---

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

---

US3412200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:09

AEID	USA-US061-2021-MRNA-1273-P30 1000018
Adverse event	POST TRAUMATIC STRESS DISORDER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:09

---

SUBJECT NOTIFIED OUR SITE  
AT 3:45 PM ON 14-APR-2021 OF  
HER HOSPITALIZATION ON  
060APR-2021 TO 14-APR-2021  
FOR SEVER DEPRESSION AND  
PTSD. SUBJECT WAS  
PRESCRIBED CONMED  
ZYPREXA 5MG TO START AS  
NEEDED ON 06-APR-2021.  
SUBJECT WILL START DAILY  
OUT PATIENT THERAPY ON  
15-APR-2021

---

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

---

US3412200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:31:09

AEID

Adverse event FATIGUE

Was this a medically-attended AE? Yes ☐  
No ☒

Was this a Solicited Adverse Reaction? Yes ☒  
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐  
No ☒

Start date (dd MMM yyyy) 12 AUG 2020

Start time (00:00-23:59) 00:00 (24 HR)

AE start date and time (derived) 12 AUG 2020 00:00

Ongoing? Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy) 18 AUG 2020

End time (00:00-23:59) 00:00 (24 HR)

AE End Date and Time (derived) 18 AUG 2020 00:00

Severity Grade 1/Mild ☒  
Grade 2/Moderate ☐  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious? Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐  
No ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:31:09

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



US3412200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:09

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 14:41:49

Generated On: 09 Jun 2021 17:31:09

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

Yes ☒

No ☐

---

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

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US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY/DEPRESSION

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 ☐  
Intraocular ☐

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US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY/DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
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 (3)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY/DEPRESSION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY / DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26	AUG 2020
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 (5)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	17 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	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)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication REMERON

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	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)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 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 (8)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication REMERON

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication REMERON

Prophylaxis Yes ☐  
No ☒

Indication WORSENING DEPRESSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONE TABLET IN THE MORNING  
IN ADDITION TO 1/2 TABLET IN  
AFTERNOON

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication ZYPREXA

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

375 of 2163

EAB) (1725)



US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication COSMETIC

Dose per administration ONE INJECTION

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

If dose unit is Other, specify ONE INJECTION PER VISIT

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

If frequency is Other, specify EVERY SIX MONTHS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 18:16:12

Generated On: 09 Jun 2021 17:31:09

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:38:50

Generated On: 09 Jun 2021 17:31:09

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3412200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:31:09

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

US3412200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:31:09

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 ☐

US3412200

Folder: SAE USA-US061-2021-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:41:49

Generated On: 09 Jun 2021 17:31:09

SAEID	USA-US061-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3412200

Folder: SAE USA-US061-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:41:49

Generated On: 09 Jun 2021 17:31:09

SAEID	USA-US061-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 12:17
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



US3412200

Folder: SAE USA-US061-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:41:49

Generated On: 09 Jun 2021 17:31:09

SAEID	USA-US061-2021-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 10:26
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

US3412200 (Prod: New Horizons Clinical Research)

**US3412200**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:31:09**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'US3412200'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:10:08

**US3412200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:35:58

US3412200

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:43:06
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	23 Sep 2020 20:09:53
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	23 Sep 2020 20:09:27
User entered '11 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:09:27
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered with 'UPDATED FROM SCREENING SHEETS' (Site from System).	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:03:04
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 19:59:56
User entered '12 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 19:59:56
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 19:58:36
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	23 Sep 2020 19:58:36
User entered '11 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 19:58:36
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 19:58:20
User entered '12 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 19:58:20
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:10:09

**US3412200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:35:58

**US3412200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'SCRN'	System	11 Aug 2020 15:35:58

US3412200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered (b) (6) 1988'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:10:10



**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '31'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'YEARS'	System	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '31'	System	11 Aug 2020 15:37:27

US3412200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:09

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:00:14
User entered 'Female (F)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:09:39
Query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' answered with 'UPDATED FROM DRIVERS LICENSE PHOTO' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:00:58
User entered 'Male (M)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:00:12
User opened query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 03:52:24
User entered 'Female (F)'		11 Aug 2020 15:36:29

US3412200

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29



**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

**US3412200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:09**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:36:29

US3412200

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:09

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:02:26
User entered '11 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:09:53
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered with 'UPDATED FROM VISIT SHEETS UPDATED' (Site from System).	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:05:40
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '12 Aug 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'Aug 2020'	System	11 Aug 2020 15:37:27



**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '2020'	System	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:37:27

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 13:10:09

**US3412200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:09**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'I'	System	11 Aug 2020 15:38:19



**US3412200**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:38:19

**US3412200**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:31:09**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:25:54

US3412200

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:45
Data point term sent to Coder	System	23 Sep 2020 14:27:14
User entered 'seasonal allergic rhinitis'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'un UNK 2015'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:32



**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'Jan 2015'	System	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '2015'	System	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:26:32

**US3412200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:26:32

US3412200

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:46
Data point term sent to Coder	System	23 Sep 2020 14:27:14
User entered 'anxiety'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49



**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'Jan 2019'	System	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '2019'	System	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:26:49

**US3412200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:26:49

US3412200

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 14:28:45
Data point term sent to Coder	System	23 Sep 2020 14:27:14
User entered 'depression'	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00
	(b) (4)	

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00



**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'Jan 2019'	System	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '2019'	System	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:27:00

**US3412200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:27:00



US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:09:27
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	23 Sep 2020 20:09:27
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:56
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:36
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	23 Sep 2020 19:58:36
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:20
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23
	(b) (4)	

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '9:56'	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '11 Aug 2020 9:56'	System	23 Sep 2020 14:28:23

US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '161.5' cm	(b) (4) Jacob sekinger (b) (4)	23 Sep 2020 14:28:23
DataPoint set to visible.	(b) (4) System	11 Aug 2020 15:38:19

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '69.9' kg	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23
DataPoint set to visible.	System	11 Aug 2020 15:38:19

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '26.79984'	System	23 Sep 2020 14:28:23
DataPoint set to visible.	System	11 Aug 2020 15:38:19

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'kg/m2'	System	23 Sep 2020 14:28:23
DataPoint set to visible.	System	11 Aug 2020 15:38:19



US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'bpm'	System	23 Sep 2020 14:28:23

US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'breaths/min'	System	23 Sep 2020 14:28:23

US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23



**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'mmHg'	System	23 Sep 2020 14:28:23

US3412200

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'mmHg'	System	23 Sep 2020 14:28:23

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26

**US3412200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26

**US3412200**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:28:36

US3412200

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:09:27
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:56
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:20
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:28:36
	(b) (4)	

US3412200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24



**US3412200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

US3412200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:09

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

**US3412200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:31:09**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

US3412200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

**US3412200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:31:09**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

US3412200

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:09

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

**US3412200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:31:09**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:24

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50



US3412200

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User closed query 'The Pregnancy date of test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	
	System	23 Sep 2020 20:09:53
User opened query 'The Pregnancy date of test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50
	(b) (4)	

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Urine (URINE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Negative (NEGATIVE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:29:50

**US3412200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	23 Sep 2020 14:29:50

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38



US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38



US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

**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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38



US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'I'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

US3412200

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:30:38

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:39:32

US3412200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 15:39:32

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:39:32

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'VISIT1'	System	11 Aug 2020 15:39:32



US3412200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User closed query 'The Randomization Date is before System the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'The Randomization Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:54:43

US3412200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:09

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:29:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:29:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 14:54:43
User entered '102609' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:54:43

US3412200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:54:43

US3412200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:09

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)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:22:58
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:33:24
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:33:17
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 12:53:05

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:09**

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)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:33:17

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:09**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:33:17

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:09**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:33:17

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:09**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:33:17



US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:31:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11
	(b) (4)	

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '09:56'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11



**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '11 Aug 2020 09:56'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '36.9' C	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '60'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'bpm'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '12'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'breaths/min'	System	23 Sep 2020 14:36:11



US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '102'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '62'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11



US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11
	(b) (4)	

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '12:05'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '11 Aug 2020 12:05'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '98.2' F	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '66'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'bpm'	System	23 Sep 2020 14:36:11



US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '12'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'breaths/min'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '102'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '68'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:11

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:36:11

US3412200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	07 Dec 2020 19:12:09
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:41

US3412200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	07 Dec 2020 19:12:09
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:09:53
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:09:27
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:56
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:20
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:41



US3412200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 20:46:44
User entered 'Yes (Y)' reason for change: Data Entry Error		23 Mar 2021 20:46:44
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

US3412200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 20:46:44
User entered '11 Aug 2020' reason for change: Data Entry Error		23 Mar 2021 20:46:44
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 20:46:44
User entered 'Urine (URINE)' reason for change: Data Entry Error		23 Mar 2021 20:46:44
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

US3412200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Signature has been broken.	(b) (4), (b) (6)	23 Mar 2021 20:46:44
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error		23 Mar 2021 20:46:44
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

US3412200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User closed query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 05:48:05
Query 'Per CDM: Please provide a response for Was FSH sample collected?' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:57:43
Signature has been broken.	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:57:39
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:57:39
User opened query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:09:00
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:36:55

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:36:55

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	23 Sep 2020 14:36:55



US3412200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:41:30

US3412200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

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)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 15:41:30

US3412200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User closed query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered '11:25'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '11 Aug 2020 11:25'	System	11 Aug 2020 15:41:30

US3412200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 15:41:30



US3412200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'ONCE'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:37:44

US3412200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:09:27
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:59:56
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:36
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:58:20
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:37:44
	(b) (4)	

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered '10:40'	Jacob sekinger (b) (4)	23 Sep 2020 14:37:44

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '11 Aug 2020 10:40'	System	23 Sep 2020 14:37:44

US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User closed query 'The Collection Date is before the Date of Informed consent. Please review and reconcile.' (Site from System).	(b) (4)	23 Sep 2020 20:09:53
User opened query 'The Collection Date is before the Date of Informed consent. Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:04:22
User entered '11 Aug 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06
	(b) (4)	

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06



US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06

US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered '10:17'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '11 Aug 2020 10:17'	System	23 Sep 2020 14:38:06

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06

US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06

US3412200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:38:06

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	23 Sep 2020 14:38:06

**US3412200**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 20:53:30



**US3412200**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	25 Aug 2020 20:53:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:09:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '6c662c05-c910-4573-acc1-22c042c5c352'	System	11 Aug 2020 16:10:06
User entered 'Yes (Y)'	System	11 Aug 2020 16:10:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:09:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '6c662c05-c910-4573-acc1-22c042c5c352'	System	11 Aug 2020 16:10:06
User entered '98.2'	System	11 Aug 2020 16:10:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:09:54', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '6c662c05-c910-4573-acc1-22c042c5c352'	System	11 Aug 2020 16:10:06
User entered 'No (N)'	System	11 Aug 2020 16:10:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:10:04', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '6c662c05-c910-4573-acc1-22c042c5c352'	System	11 Aug 2020 16:10:06
User entered '11 Aug 2020 12:10'	System	11 Aug 2020 16:10:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 11:45'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 14:15'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:44:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7dd1d6b8-ae93-4f29-a8d0-de7a06d3686e'	System	11 Aug 2020 22:46:33
User entered 'Yes (Y)'	System	11 Aug 2020 22:46:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:46:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7dd1d6b8-ae93-4f29-a8d0-de7a06d3686e'	System	11 Aug 2020 22:46:33
User entered '98.7'	System	11 Aug 2020 22:46:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:46:25', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7dd1d6b8-ae93-4f29-a8d0-de7a06d3686e'	System	11 Aug 2020 22:46:33
User entered 'No (N)'	System	11 Aug 2020 22:46:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:46:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7dd1d6b8-ae93-4f29-a8d0-de7a06d3686e'	System	11 Aug 2020 22:46:33
User entered '11 Aug 2020 18:46'	System	11 Aug 2020 22:46:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 15:10'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 2'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd593d78a-9f01-45f1-b82e-334d65e323c2'	System	12 Aug 2020 20:40:25
User entered 'Yes (Y)'	System	12 Aug 2020 20:40:25

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:12', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd593d78a-9f01-45f1-b82e-334d65e323c2'	System	12 Aug 2020 20:40:25
User entered '98.3'	System	12 Aug 2020 20:40:25

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd593d78a-9f01-45f1-b82e-334d65e323c2'	System	12 Aug 2020 20:40:25
User entered 'No (N)'	System	12 Aug 2020 20:40:25

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd593d78a-9f01-45f1-b82e-334d65e323c2'	System	12 Aug 2020 20:40:25
User entered '12 Aug 2020 16:40'	System	12 Aug 2020 20:40:25

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 3'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e508a9f2-9785-431a-a251-99c755482c2c'	System	14 Aug 2020 01:08:33
User entered 'Yes (Y)'	System	14 Aug 2020 01:08:33



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:21', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e508a9f2-9785-431a-a251-99c755482c2c'	System	14 Aug 2020 01:08:33
User entered '98.0'	System	14 Aug 2020 01:08:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:24', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e508a9f2-9785-431a-a251-99c755482c2c'	System	14 Aug 2020 01:08:33
User entered 'No (N)'	System	14 Aug 2020 01:08:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:27', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e508a9f2-9785-431a-a251-99c755482c2c'	System	14 Aug 2020 01:08:33
User entered '13 Aug 2020 21:08'	System	14 Aug 2020 01:08:33

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 4'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f5c8dae9-4bbd-4059-ab1b-d6acf25a21e5'	System	15 Aug 2020 02:11:29
User entered 'Yes (Y)'	System	15 Aug 2020 02:11:29

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f5c8dae9-4bbd-4059-ab1b-d6acf25a21e5'	System	15 Aug 2020 02:11:29
User entered '97.3'	System	15 Aug 2020 02:11:29



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f5c8dae9-4bbd-4059-ab1b-d6acf25a21e5'	System	15 Aug 2020 02:11:29
User entered 'No (N)'	System	15 Aug 2020 02:11:29

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f5c8dae9-4bbd-4059-ab1b-d6acf25a21e5'	System	15 Aug 2020 02:11:29
User entered '14 Aug 2020 22:11'	System	15 Aug 2020 02:11:29

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 5'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 6'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:34', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2ac760b0-880f-451f-9362-8df817c8a085'	System	16 Aug 2020 23:09:45
User entered 'Yes (Y)'	System	16 Aug 2020 23:09:45

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:38', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2ac760b0-880f-451f-9362-8df817c8a085'	System	16 Aug 2020 23:09:45
User entered '98.2'	System	16 Aug 2020 23:09:45



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:41', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2ac760b0-880f-451f-9362-8df817c8a085'	System	16 Aug 2020 23:09:45
User entered 'No (N)'	System	16 Aug 2020 23:09:45

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2ac760b0-880f-451f-9362-8df817c8a085'	System	16 Aug 2020 23:09:45
User entered '16 Aug 2020 19:09'	System	16 Aug 2020 23:09:45

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 7'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:17:52', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '56c53486-2d22-4930-8775-5b1d76f33958'	System	17 Aug 2020 23:18:05
User entered 'Yes (Y)'	System	17 Aug 2020 23:18:05

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:17:55', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '56c53486-2d22-4930-8775-5b1d76f33958'	System	17 Aug 2020 23:18:05
User entered '98.5'	System	17 Aug 2020 23:18:05

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:17:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '56c53486-2d22-4930-8775-5b1d76f33958'	System	17 Aug 2020 23:18:05
User entered 'No (N)'	System	17 Aug 2020 23:18:05



US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '56c53486-2d22-4930-8775-5b1d76f33958'	System	17 Aug 2020 23:18:05
User entered '17 Aug 2020 19:18'	System	17 Aug 2020 23:18:05

US3412200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 16:13:04

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered 'Yes (Y)'	System	11 Aug 2020 16:13:04

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:25', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered '10'	System	11 Aug 2020 16:13:04

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:29', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered 'Yes (Y)'	System	11 Aug 2020 16:13:04



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered '17'	System	11 Aug 2020 16:13:04

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:12:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered 'None (1)'	System	11 Aug 2020 16:13:04

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:01', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '176c7fbd-c88a-49e9-a78e-0bd62f359cc0'	System	11 Aug 2020 16:13:04
User entered '11 Aug 2020 12:13'	System	11 Aug 2020 16:13:04

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 11:45'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 14:15'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:46:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:48:24', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered 'No (N)'	System	11 Aug 2020 23:02:02



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:51:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered 'Yes (Y)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:51:42', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered '25'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:52:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '0f9646d9-23d0-4ce9-8aa8-593ce7e41f82'	System	11 Aug 2020 23:02:02
User entered '11 Aug 2020 18:53'	System	11 Aug 2020 23:02:02

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 15:10'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 2'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:45', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ecb1946b-6cd9-4124-aae7-84dfe31b312b'	System	12 Aug 2020 20:41:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	12 Aug 2020 20:41:45



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ecb1946b-6cd9-4124-aae7-84dfe31b312b'	System	12 Aug 2020 20:41:45
User entered 'No (N)'	System	12 Aug 2020 20:41:45

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:40:53', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ecb1946b-6cd9-4124-aae7-84dfe31b312b'	System	12 Aug 2020 20:41:45
User entered 'No (N)'	System	12 Aug 2020 20:41:45

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:41:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ecb1946b-6cd9-4124-aae7-84dfe31b312b'	System	12 Aug 2020 20:41:45
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 20:41:45

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:41:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ecb1946b-6cd9-4124-aae7-84dfe31b312b'	System	12 Aug 2020 20:41:45
User entered '12 Aug 2020 16:41'	System	12 Aug 2020 20:41:45

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 3'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '62a8f459-f5b3-4bfa-a0fe-ba887651e203'	System	14 Aug 2020 01:08:59
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 01:08:59



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:47', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '62a8f459-f5b3-4bfa-a0fe-ba887651e203'	System	14 Aug 2020 01:08:59
User entered 'No (N)'	System	14 Aug 2020 01:08:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:52', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '62a8f459-f5b3-4bfa-a0fe-ba887651e203'	System	14 Aug 2020 01:08:59
User entered 'No (N)'	System	14 Aug 2020 01:08:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:55', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '62a8f459-f5b3-4bfa-a0fe-ba887651e203'	System	14 Aug 2020 01:08:59
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 01:08:59

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:08:58', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '62a8f459-f5b3-4bfa-a0fe-ba887651e203'	System	14 Aug 2020 01:08:59
User entered '13 Aug 2020 21:08'	System	14 Aug 2020 01:08:59

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 4'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:40', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b2bec1be-39d2-46e1-84cb-67310e4528e1'	System	15 Aug 2020 02:12:05
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 02:12:05



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:46', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b2bec1be-39d2-46e1-84cb-67310e4528e1'	System	15 Aug 2020 02:12:05
User entered 'No (N)'	System	15 Aug 2020 02:12:05

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:50', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b2bec1be-39d2-46e1-84cb-67310e4528e1'	System	15 Aug 2020 02:12:05
User entered 'No (N)'	System	15 Aug 2020 02:12:05

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:11:56', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b2bec1be-39d2-46e1-84cb-67310e4528e1'	System	15 Aug 2020 02:12:05
User entered 'None (1)'	System	15 Aug 2020 02:12:05

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b2bec1be-39d2-46e1-84cb-67310e4528e1'	System	15 Aug 2020 02:12:05
User entered '14 Aug 2020 22:12'	System	15 Aug 2020 02:12:05

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 5'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 6'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:47', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3860564e-be3c-48d4-8400-c8714d9ef785'	System	16 Aug 2020 23:09:57
User entered 'None (1)'	System	16 Aug 2020 23:09:57

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3860564e-be3c-48d4-8400-c8714d9ef785'	System	16 Aug 2020 23:09:57
User entered 'No (N)'	System	16 Aug 2020 23:09:57

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:51', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3860564e-be3c-48d4-8400-c8714d9ef785'	System	16 Aug 2020 23:09:57
User entered 'No (N)'	System	16 Aug 2020 23:09:57

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:54', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3860564e-be3c-48d4-8400-c8714d9ef785'	System	16 Aug 2020 23:09:57
User entered 'None (1)'	System	16 Aug 2020 23:09:57

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:09:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3860564e-be3c-48d4-8400-c8714d9ef785'	System	16 Aug 2020 23:09:57
User entered '16 Aug 2020 19:09'	System	16 Aug 2020 23:09:57

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 7'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:05', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd7f64b8c-29cf-4d9f-940e-76d9311a6846'	System	17 Aug 2020 23:18:19
User entered 'None (1)'	System	17 Aug 2020 23:18:19

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd7f64b8c-29cf-4d9f-940e-76d9311a6846'	System	17 Aug 2020 23:18:19
User entered 'No (N)'	System	17 Aug 2020 23:18:19

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:09', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd7f64b8c-29cf-4d9f-940e-76d9311a6846'	System	17 Aug 2020 23:18:19
User entered 'No (N)'	System	17 Aug 2020 23:18:19

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:12', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd7f64b8c-29cf-4d9f-940e-76d9311a6846'	System	17 Aug 2020 23:18:19
User entered 'None (1)'	System	17 Aug 2020 23:18:19

US3412200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd7f64b8c-29cf-4d9f-940e-76d9311a6846'	System	17 Aug 2020 23:18:19
User entered '17 Aug 2020 19:18'	System	17 Aug 2020 23:18:19

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:26', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:30', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:35', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:40', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:13:45', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'None (0)'	System	11 Aug 2020 16:14:33

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:14:25', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered 'No (N)'	System	11 Aug 2020 16:14:33



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T12:14:30', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7950aa2b-a3df-443d-80bd-a73e9eb063e9'	System	11 Aug 2020 16:14:33
User entered '11 Aug 2020 12:14'	System	11 Aug 2020 16:14:33

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 11:45'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 14:15'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:20', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:24', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:29', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'None (0)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered 'No (N)'	System	11 Aug 2020 23:02:02

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-11T18:53:34', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd945afbc-f42b-4354-a586-4eba8473c9c6'	System	11 Aug 2020 23:02:02
User entered '11 Aug 2020 18:53'	System	11 Aug 2020 23:02:02

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Aug 2020 15:10'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 2'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:41:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'None (0)'	System	12 Aug 2020 20:42:17



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:41:55', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'Some interference with activity (2)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:41:58', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'None (0)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:42:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'None (0)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:42:04', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'None (0)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:42:06', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'None (0)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:42:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered 'No (N)'	System	12 Aug 2020 20:42:17

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-12T16:42:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '181d6af9-0b02-42aa-8f90-5712c79218b6'	System	12 Aug 2020 20:42:17
User entered '12 Aug 2020 16:42'	System	12 Aug 2020 20:42:17

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:41:30



**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 3'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:03', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'None (0)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:05', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'No interference with activity (1)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:08', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'None (0)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'None (0)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'None (0)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'None (0)'	System	14 Aug 2020 01:09:22



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:19', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered 'No (N)'	System	14 Aug 2020 01:09:22

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-13T21:09:21', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '168eee96-0a6e-4937-a54b-c44166c086bf'	System	14 Aug 2020 01:09:22
User entered '13 Aug 2020 21:09'	System	14 Aug 2020 01:09:22

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 4'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'No interference with activity (1)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'No interference with activity (1)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'None (0)'	System	15 Aug 2020 02:12:48



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'None (0)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'None (0)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered 'No (N)'	System	15 Aug 2020 02:12:48

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-14T22:12:45', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ac196e58-b812-4d2d-b1d3-249f9a6acbee'	System	15 Aug 2020 02:12:48
User entered '14 Aug 2020 22:12'	System	15 Aug 2020 02:12:48

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 5'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 6'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'No interference with activity (1)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:05', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'Some interference with activity (2)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'None (0)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'None (0)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'None (0)'	System	16 Aug 2020 23:10:28



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:20', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'None (0)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:23', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered 'No (N)'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-16T19:10:25', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07d0c10e-e5d1-48c6-9dd1-4023a1eb2f52'	System	16 Aug 2020 23:10:28
User entered '16 Aug 2020 19:10'	System	16 Aug 2020 23:10:28

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 7'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:20', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'No interference with activity (1)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:24', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'No interference with activity (1)'	System	17 Aug 2020 23:18:43



US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:27', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'No interference with activity (1)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:29', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'None (0)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:31', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'None (0)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'None (0)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:38', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered 'Yes (Y)'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-17T19:18:41', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e4613d28-c773-497b-a175-d496c34f2f91'	System	17 Aug 2020 23:18:43
User entered '17 Aug 2020 19:18'	System	17 Aug 2020 23:18:43

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:41:30

US3412200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:41:30



US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	16 Aug 2020 23:10:28
User entered 'Day 8'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:31:09

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b0a10d90-aab4-4d1c-811c-f07f406873b9'	System	19 Aug 2020 09:13:09
User entered 'No interference with activity (1)'	System	19 Aug 2020 09:13:09

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:05', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b0a10d90-aab4-4d1c-811c-f07f406873b9'	System	19 Aug 2020 09:13:09
User entered '19 Aug 2020 05:13'	System	19 Aug 2020 09:13:09

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:10:28

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	17 Aug 2020 23:18:43
User entered 'Day 9'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:14:40', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '4afd77ac-25d2-4686-a784-1d8854a95757'	System	20 Aug 2020 09:14:55
User entered 'None (0)'	System	20 Aug 2020 09:14:55

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:14:44', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '4afd77ac-25d2-4686-a784-1d8854a95757'	System	20 Aug 2020 09:14:55
User entered '20 Aug 2020 05:14'	System	20 Aug 2020 09:14:55



US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	16 Aug 2020 23:10:28
User entered 'Day 8'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '50988736-953a-4d0d-b629-da839ec374b8'	System	19 Aug 2020 09:13:19
User entered 'No interference with activity (1)'	System	19 Aug 2020 09:13:19

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '50988736-953a-4d0d-b629-da839ec374b8'	System	19 Aug 2020 09:13:19
User entered '19 Aug 2020 05:13'	System	19 Aug 2020 09:13:19

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:10:28

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	17 Aug 2020 23:18:43
User entered 'Day 9'	System	17 Aug 2020 23:18:43



US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:31:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:14:48', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f18f7d07-8345-4eaf-9d2b-4ea7cd4f8ba3'	System	20 Aug 2020 09:15:05
User entered 'None (0)'	System	20 Aug 2020 09:15:05

US3412200

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:14:50', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f18f7d07-8345-4eaf-9d2b-4ea7cd4f8ba3'	System	20 Aug 2020 09:15:05
User entered '20 Aug 2020 05:14'	System	20 Aug 2020 09:15:05

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 23:18:43

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	17 Aug 2020 23:18:43
User entered 'Day 8'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:31:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:19', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b52cae7b-1386-42f1-9763-92c1e74880f9'	System	19 Aug 2020 09:13:24
User entered 'None (0)'	System	19 Aug 2020 09:13:24

US3412200

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b52cae7b-1386-42f1-9763-92c1e74880f9'	System	19 Aug 2020 09:13:24
User entered '19 Aug 2020 05:13'	System	19 Aug 2020 09:13:24

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 23:18:43



**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	16 Aug 2020 23:10:28
User entered 'Day 8'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:29', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '52029c64-9c68-4855-9227-40868b68b096'	System	19 Aug 2020 09:13:34
User entered 'No (N)'	System	19 Aug 2020 09:13:34

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-19T05:13:31', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '52029c64-9c68-4855-9227-40868b68b096'	System	19 Aug 2020 09:13:34
User entered '19 Aug 2020 05:13'	System	19 Aug 2020 09:13:34

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:10:28

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:10:28

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	17 Aug 2020 23:18:43
User entered 'Day 9'	System	17 Aug 2020 23:18:43

US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:15:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e7f27034-4221-4511-9019-3fb1a4b2cb18'	System	20 Aug 2020 09:15:06
User entered 'No (N)'	System	20 Aug 2020 09:15:06



US3412200

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-08-20T05:15:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e7f27034-4221-4511-9019-3fb1a4b2cb18'	System	20 Aug 2020 09:15:06
User entered '20 Aug 2020 05:15'	System	20 Aug 2020 09:15:06

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 23:18:43

**US3412200**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 23:18:43

**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:47

**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:47

**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:47

**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:47

**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:43:52



**US3412200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	01 Sep 2020 19:43:52

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:05

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:05

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:05

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:05

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:09

**US3412200**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	01 Sep 2020 19:44:09

**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:24



**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:24

**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:24

**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:24

**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:44:28

**US3412200**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	01 Sep 2020 19:44:28

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:24:10

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:24:10

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:24:10



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'VISIT2'	System	08 Sep 2020 12:24:10

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '07:24'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '8 Sep 2020 07:24'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '36.9' C	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '68'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'bpm'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '16'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'breaths/min'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '118'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '70'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '9:21'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '8 Sep 2020 9:21'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '98.1' F	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '66'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'bpm'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '16'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'breaths/min'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '110'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '78'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:17



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'mmHg'	System	23 Sep 2020 14:40:17

US3412200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:37

US3412200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:37

US3412200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Urine (URINE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Negative (NEGATIVE)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

US3412200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:09

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	23 Sep 2020 14:40:55

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13

US3412200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

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)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 12:52:13

US3412200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '08:50'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '08 Sep 2020 08:50'	System	08 Sep 2020 12:52:13

US3412200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:52:13

US3412200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'ONCE'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:09**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:20

US3412200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:20

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8:12'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:20



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '8 Sep 2020 8:12'	System	23 Sep 2020 14:41:20

US3412200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '8 Sep 2020'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

US3412200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '08:18'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '8 Sep 2020 08:18'	System	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37



**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	23 Sep 2020 14:41:37

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:15

**US3412200**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	15 Sep 2020 19:29:15

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:27:21', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '94b2095a-535e-43de-b0a9-58a73bd462ca'	System	08 Sep 2020 13:27:38
User entered 'Yes (Y)'	System	08 Sep 2020 13:27:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:27:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '94b2095a-535e-43de-b0a9-58a73bd462ca'	System	08 Sep 2020 13:27:38
User entered '98.1'	System	08 Sep 2020 13:27:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:27:31', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '94b2095a-535e-43de-b0a9-58a73bd462ca'	System	08 Sep 2020 13:27:38
User entered 'No (N)'	System	08 Sep 2020 13:27:38



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:27:34', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '94b2095a-535e-43de-b0a9-58a73bd462ca'	System	08 Sep 2020 13:27:38
User entered '08 Sep 2020 09:27'	System	08 Sep 2020 13:27:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 09:10'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:58:53', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b1d2c22-3be4-4900-8409-efe7b656fc68'	System	08 Sep 2020 20:59:26
User entered 'Yes (Y)'	System	08 Sep 2020 20:59:26

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:58:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b1d2c22-3be4-4900-8409-efe7b656fc68'	System	08 Sep 2020 20:59:26
User entered '98.7'	System	08 Sep 2020 20:59:26

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:01', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b1d2c22-3be4-4900-8409-efe7b656fc68'	System	08 Sep 2020 20:59:26
User entered 'No (N)'	System	08 Sep 2020 20:59:26

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:03', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b1d2c22-3be4-4900-8409-efe7b656fc68'	System	08 Sep 2020 20:59:26
User entered '08 Sep 2020 16:59'	System	08 Sep 2020 20:59:26



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 12:35'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 2'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-09T18:33:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e9819ed7-409d-4472-8a44-8014a896de0c'	System	09 Sep 2020 22:33:46
User entered 'Yes (Y)'	System	09 Sep 2020 22:33:46

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-09T18:33:38', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e9819ed7-409d-4472-8a44-8014a896de0c'	System	09 Sep 2020 22:33:46
User entered '99.6'	System	09 Sep 2020 22:33:46

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-09T18:33:40', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e9819ed7-409d-4472-8a44-8014a896de0c'	System	09 Sep 2020 22:33:46
User entered 'No (N)'	System	09 Sep 2020 22:33:46

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-09T18:33:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e9819ed7-409d-4472-8a44-8014a896de0c'	System	09 Sep 2020 22:33:46
User entered '09 Sep 2020 18:33'	System	09 Sep 2020 22:33:46

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 3'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '194de8e1-dcb4-43e1-83d1-8414ff7a5b7d'	System	10 Sep 2020 21:54:35
User entered 'Yes (Y)'	System	10 Sep 2020 21:54:35

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:27', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '194de8e1-dcb4-43e1-83d1-8414ff7a5b7d'	System	10 Sep 2020 21:54:35
User entered '98.7'	System	10 Sep 2020 21:54:35

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:29', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '194de8e1-dcb4-43e1-83d1-8414ff7a5b7d'	System	10 Sep 2020 21:54:35
User entered 'No (N)'	System	10 Sep 2020 21:54:35

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '194de8e1-dcb4-43e1-83d1-8414ff7a5b7d'	System	10 Sep 2020 21:54:35
User entered '10 Sep 2020 17:54'	System	10 Sep 2020 21:54:35

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 4'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '941568fd-2848-4c9c-bfea-f02f102be02a'	System	12 Sep 2020 00:59:38
User entered 'No (N)'	System	12 Sep 2020 00:59:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:31', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '941568fd-2848-4c9c-bfea-f02f102be02a'	System	12 Sep 2020 00:59:38
User entered 'No (N)'	System	12 Sep 2020 00:59:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:35', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '941568fd-2848-4c9c-bfea-f02f102be02a'	System	12 Sep 2020 00:59:38
User entered '11 Sep 2020 20:59'	System	12 Sep 2020 00:59:38

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 5'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:35:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f2561d23-e28d-4fac-9326-9b7274f888d7'	System	13 Sep 2020 13:35:50
User entered 'Yes (Y)'	System	13 Sep 2020 13:35:50



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:35:41', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f2561d23-e28d-4fac-9326-9b7274f888d7'	System	13 Sep 2020 13:35:50
User entered '97.8'	System	13 Sep 2020 13:35:50

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:35:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f2561d23-e28d-4fac-9326-9b7274f888d7'	System	13 Sep 2020 13:35:50
User entered 'No (N)'	System	13 Sep 2020 13:35:50

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:35:48', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f2561d23-e28d-4fac-9326-9b7274f888d7'	System	13 Sep 2020 13:35:50
User entered '13 Sep 2020 09:35'	System	13 Sep 2020 13:35:50

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 6'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 7'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:27:39', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2fc82156-1aaf-4d93-9d1c-e2cc7f98335f'	System	08 Sep 2020 13:28:41
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 13:28:41

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:24', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2fc82156-1aaf-4d93-9d1c-e2cc7f98335f'	System	08 Sep 2020 13:28:41
User entered 'No (N)'	System	08 Sep 2020 13:28:41

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:27', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2fc82156-1aaf-4d93-9d1c-e2cc7f98335f'	System	08 Sep 2020 13:28:41
User entered 'No (N)'	System	08 Sep 2020 13:28:41

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2fc82156-1aaf-4d93-9d1c-e2cc7f98335f'	System	08 Sep 2020 13:28:41
User entered 'None (1)'	System	08 Sep 2020 13:28:41

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:39', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2fc82156-1aaf-4d93-9d1c-e2cc7f98335f'	System	08 Sep 2020 13:28:41
User entered '08 Sep 2020 09:28'	System	08 Sep 2020 13:28:41

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 09:10'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 21:00:29

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered 'No (N)'	System	08 Sep 2020 21:00:29

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered 'Yes (Y)'	System	08 Sep 2020 21:00:29

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T16:59:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered '40'	System	08 Sep 2020 21:00:29

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:04', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered 'None (1)'	System	08 Sep 2020 21:00:29

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:06', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '2cfc2a05-0d5c-488b-989c-b942434657df'	System	08 Sep 2020 21:00:29
User entered '08 Sep 2020 17:00'	System	08 Sep 2020 21:00:29

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 12:35'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 2'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 3'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:36', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 22:03:19

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:39', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered 'No (N)'	System	10 Sep 2020 22:03:19

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T17:54:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered 'Yes (Y)'	System	10 Sep 2020 22:03:19

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered '40'	System	10 Sep 2020 22:03:19

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered 'None (1)'	System	10 Sep 2020 22:03:19



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:17', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '132e7231-f109-4055-8620-b87f8b6ab077'	System	10 Sep 2020 22:03:19
User entered '10 Sep 2020 18:03'	System	10 Sep 2020 22:03:19

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 4'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:39', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '71dfdd49-dbeb-40a8-ba52-f763133f619c'	System	12 Sep 2020 00:59:57
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 00:59:57

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:42', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '71dfdd49-dbeb-40a8-ba52-f763133f619c'	System	12 Sep 2020 00:59:57
User entered 'No (N)'	System	12 Sep 2020 00:59:57

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '71dfdd49-dbeb-40a8-ba52-f763133f619c'	System	12 Sep 2020 00:59:57
User entered 'No (N)'	System	12 Sep 2020 00:59:57

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:52', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '71dfdd49-dbeb-40a8-ba52-f763133f619c'	System	12 Sep 2020 00:59:57
User entered 'None (1)'	System	12 Sep 2020 00:59:57



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T20:59:54', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '71dfdd49-dbeb-40a8-ba52-f763133f619c'	System	12 Sep 2020 00:59:57
User entered '11 Sep 2020 20:59'	System	12 Sep 2020 00:59:57

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 5'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:36:30', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 13:37:49

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:36:33', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered 'Yes (Y)'	System	13 Sep 2020 13:37:49

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:37:30', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered '60'	System	13 Sep 2020 13:37:49

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:37:40', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered 'No (N)'	System	13 Sep 2020 13:37:49



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:37:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered 'None (1)'	System	13 Sep 2020 13:37:49

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:37:45', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b1b49ad5-5843-4fbd-a3c2-39ff8257a7ea'	System	13 Sep 2020 13:37:49
User entered '13 Sep 2020 09:37'	System	13 Sep 2020 13:37:49

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 6'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 7'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:43', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:44', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:45', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:47', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:48', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:50', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'None (0)'	System	08 Sep 2020 13:28:56

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:52', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered 'No (N)'	System	08 Sep 2020 13:28:56



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T09:28:54', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f540bda3-fb1e-431a-bb78-a0361f304b4c'	System	08 Sep 2020 13:28:56
User entered '08 Sep 2020 09:28'	System	08 Sep 2020 13:28:56

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 09:10'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 11:40'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:09', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'None (0)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:20', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered 'No (N)'	System	08 Sep 2020 21:00:46

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-08T17:00:22', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3e794e1e-eb5f-4694-8031-aff56336297b'	System	08 Sep 2020 21:00:46
User entered '08 Sep 2020 17:00'	System	08 Sep 2020 21:00:46

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '08 Sep 2020 12:35'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 2'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:13



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 3'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:23', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'None (0)'	System	10 Sep 2020 22:03:47

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:26', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'No interference with activity (1)'	System	10 Sep 2020 22:03:47

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'None (0)'	System	10 Sep 2020 22:03:47

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'None (0)'	System	10 Sep 2020 22:03:47

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:34', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'None (0)'	System	10 Sep 2020 22:03:47

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'No interference with activity (1)'	System	10 Sep 2020 22:03:47



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:39', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered 'No (N)'	System	10 Sep 2020 22:03:47

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-10T18:03:42', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f6a8b782-37af-4a16-b7b9-7327188d61dd'	System	10 Sep 2020 22:03:47
User entered '10 Sep 2020 18:03'	System	10 Sep 2020 22:03:47

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 4'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:04', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffdc4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffdc4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:09', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffdc4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffd4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffdc4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffdc4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'None (0)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffd4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered 'No (N)'	System	12 Sep 2020 01:00:22

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-11T21:00:20', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd5dffd4-93d4-41b5-ae09-1fe93c3d7daa'	System	12 Sep 2020 01:00:22
User entered '11 Sep 2020 21:00'	System	12 Sep 2020 01:00:22

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 5'	System	08 Sep 2020 12:52:13



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:37:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'No interference with activity (1)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'No interference with activity (1)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:04', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'None (0)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:06', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'None (0)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'None (0)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:09', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eebe63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'None (0)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered 'No (N)'	System	13 Sep 2020 13:38:16

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-09-13T09:38:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '5eeeb63-0da4-444f-9439-75de64bb21e1'	System	13 Sep 2020 13:38:16
User entered '13 Sep 2020 09:38'	System	13 Sep 2020 13:38:16



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 6'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:13

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	08 Sep 2020 12:52:13
User entered 'Day 7'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06



US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

US3412200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:13

**US3412200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:13



**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:29

**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:29

**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:29

**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:29

**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:36

**US3412200**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	15 Sep 2020 19:29:36

**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 17:36:33

**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered '22 Sep 2020'	Mason Urban (b) (4)	22 Sep 2020 17:36:33



**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Sep 2020 17:36:33

**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered empty.	Mason Urban (b) (4)	22 Sep 2020 17:36:33

**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Sep 2020 17:36:37

**US3412200**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	22 Sep 2020 17:36:37

**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	30 Sep 2020 21:06:46

**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered '30 Sep 2020'	Mason Urban (b) (4)	30 Sep 2020 21:06:46

**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	30 Sep 2020 21:06:46

**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered empty.	Mason Urban (b) (4)	30 Sep 2020 21:06:46



**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:30
User entered 'Yes (Y)'	Mason Urban (b) (4)	30 Sep 2020 21:06:54

**US3412200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	30 Sep 2020 21:06:54

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 21:02:24

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 21:02:24

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	06 Oct 2020 21:02:24

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'VISIT3'	System	06 Oct 2020 21:02:24

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)'	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32



**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32



**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	06 Oct 2020 21:02:32

US3412200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty.	Steven Anderson (b) (4)	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered empty.	System	06 Oct 2020 21:02:32

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10

US3412200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	07 Dec 2020 19:13:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 21:02:44



US3412200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	07 Dec 2020 19:13:36
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 21:02:44

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 21:03:05

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '06 Oct 2020'	Steven Anderson (b) (4)	06 Oct 2020 21:03:05

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered '15:20'	Steven Anderson (b) (4)	06 Oct 2020 21:03:05

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '06 Oct 2020 15:20'	System	06 Oct 2020 21:03:05

US3412200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:45:31
User entered 'Yes (Y)'	Steven Anderson (b) (4)	06 Oct 2020 21:03:10

**US3412200**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered '1'	System	06 Oct 2020 21:03:10

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 64'	System	11 Aug 2020 15:41:30



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 15:41:30

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 15:41:30

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 71'	System	11 Aug 2020 15:41:30

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with 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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

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**Generated On: 09 Jun 2021 17:31:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
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**US3412200**

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

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**US3412200**

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**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 15:41:30

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 15:41:30

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 78'	System	11 Aug 2020 15:41:30



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with 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)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

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**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:30:20
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 92'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-08T09:29:48', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1391a4b0-5637-4423-90bd-ac9ea0744b0b'	System	08 Nov 2020 14:30:40
User entered 'No (N)'	System	08 Nov 2020 14:30:40

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-08T09:29:54', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1391a4b0-5637-4423-90bd-ac9ea0744b0b'	System	08 Nov 2020 14:30:40
User entered 'Yes (Y)'	System	08 Nov 2020 14:30:40

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-08T09:30:06', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1391a4b0-5637-4423-90bd-ac9ea0744b0b'	System	08 Nov 2020 14:30:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 14:30:40

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-08T09:30:27', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1391a4b0-5637-4423-90bd-ac9ea0744b0b'	System	08 Nov 2020 14:30:40
User entered '08 Nov 2020 09:30:27'	System	08 Nov 2020 14:30:40



**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered 'Day 99'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-15T04:03:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3165feb9-d26f-4bd2-824a-239d99bbf5a3'	System	15 Nov 2020 09:03:44
User entered 'No (N)'	System	15 Nov 2020 09:03:44

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-15T04:03:36', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3165feb9-d26f-4bd2-824a-239d99bbf5a3'	System	15 Nov 2020 09:03:44
User entered 'No (N)'	System	15 Nov 2020 09:03:44

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-15T04:03:42', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '3165feb9-d26f-4bd2-824a-239d99bbf5a3'	System	15 Nov 2020 09:03:44
User entered '15 Nov 2020 04:03:42'	System	15 Nov 2020 09:03:44

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 15:41:30

**US3412200**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:06
Data entry locked.	System	11 Aug 2020 15:41:30
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 15:41:30



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2020-11-23T05:42:09', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f62bcb9e-f35b-4de4-bd0a-cdff8ca60b9'	System	23 Nov 2020 10:42:23
User entered 'No (N)'	System	23 Nov 2020 10:42:23

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2020-11-23T05:42:12', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f62bcb9e-f35b-4de4-bd0a-cdff8ca60b9'	System	23 Nov 2020 10:42:23
User entered 'No (N)'	System	23 Nov 2020 10:42:23

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-23T05:42:18', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'f62bcb9e-f35b-4de4-bd0a-cdff8ca60b9'	System	23 Nov 2020 10:42:23
User entered '23 Nov 2020 05:42:18'	System	23 Nov 2020 10:42:23

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2020-11-29T14:33:01', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b8af70d-a1e9-4916-a808-d1e89238569e'	System	29 Nov 2020 19:33:26
User entered 'No (N)'	System	29 Nov 2020 19:33:26



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2020-11-29T14:33:07', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b8af70d-a1e9-4916-a808-d1e89238569e'	System	29 Nov 2020 19:33:26
User entered 'Yes (Y)'	System	29 Nov 2020 19:33:26

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Please 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 (437e61323bb8d485)', Time: '2020-11-29T14:33:12', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b8af70d-a1e9-4916-a808-d1e89238569e'	System	29 Nov 2020 19:33:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 19:33:26

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-11-29T14:33:17', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '7b8af70d-a1e9-4916-a808-d1e89238569e' User entered '29 Nov 2020 14:33:17'	System	29 Nov 2020 19:33:26
	System	29 Nov 2020 19:33:26

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2020-12-06T10:01:53', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd3b66066-67e0-47c9-b9c7-c721e90512e0'	System	06 Dec 2020 15:02:01
User entered 'No (N)'	System	06 Dec 2020 15:02:01

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2020-12-06T10:01:56', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd3b66066-67e0-47c9-b9c7-c721e90512e0'	System	06 Dec 2020 15:02:01
User entered 'No (N)'	System	06 Dec 2020 15:02:01



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-12-06T10:01:58', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'd3b66066-67e0-47c9-b9c7-c721e90512e0' User entered '06 Dec 2020 10:01:58'	System	06 Dec 2020 15:02:01
	System	06 Dec 2020 15:02:01

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2020-12-11T19:28:50', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e398decb-0803-4741-bd23-bbd8c6d7255c'	System	12 Dec 2020 00:29:19
User entered 'No (N)'	System	12 Dec 2020 00:29:19

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2020-12-11T19:29:10', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e398decb-0803-4741-bd23-bbd8c6d7255c'	System	12 Dec 2020 00:29:19
User entered 'No (N)'	System	12 Dec 2020 00:29:19

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-12-11T19:29:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'e398decb-0803-4741-bd23-bbd8c6d7255c'	System	12 Dec 2020 00:29:19
User entered '11 Dec 2020 19:29:14'	System	12 Dec 2020 00:29:19

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2020-12-19T15:43:42', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a344ca3b-cef2-4fe0-bf93-e5b789a21398'	System	19 Dec 2020 20:43:50
User entered 'No (N)'	System	19 Dec 2020 20:43:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2020-12-19T15:43:46', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a344ca3b-cef2-4fe0-bf93-e5b789a21398'	System	19 Dec 2020 20:43:50
User entered 'No (N)'	System	19 Dec 2020 20:43:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2020-12-19T15:43:49', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a344ca3b-cef2-4fe0-bf93-e5b789a21398' User entered '19 Dec 2020 15:43:49'	System	19 Dec 2020 20:43:50
	System	19 Dec 2020 20:43:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-01-18T09:41:51', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b9b186b0-5a39-432a-b3a3-cb1a6d8d89d0'	System	18 Jan 2021 14:42:00
User entered 'No (N)'	System	18 Jan 2021 14:42:00

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-01-18T09:41:55', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b9b186b0-5a39-432a-b3a3-cb1a6d8d89d0'	System	18 Jan 2021 14:42:00
User entered 'No (N)'	System	18 Jan 2021 14:42:00

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-01-18T09:41:57', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'b9b186b0-5a39-432a-b3a3-cb1a6d8d89d0'	System	18 Jan 2021 14:42:00
User entered '18 Jan 2021 09:41:57'	System	18 Jan 2021 14:42:00

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-01-21T04:33:15', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07c90617-bb05-4057-8134-55715dd4e512'	System	21 Jan 2021 09:33:47
User entered 'No (N)'	System	21 Jan 2021 09:33:47



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-01-21T04:33:37', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07c90617-bb05-4057-8134-55715dd4e512'	System	21 Jan 2021 09:33:47
User entered 'No (N)'	System	21 Jan 2021 09:33:47

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-01-21T04:33:41', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '07c90617-bb05-4057-8134-55715dd4e512'	System	21 Jan 2021 09:33:47
User entered '21 Jan 2021 04:33:41'	System	21 Jan 2021 09:33:47

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-01-28T05:02:02', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a996930c-0dcb-48da-b837-2e13a5c84b86'	System	28 Jan 2021 10:02:18
User entered 'No (N)'	System	28 Jan 2021 10:02:18

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-01-28T05:02:11', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a996930c-0dc6-48da-b837-2e13a5c84b86'	System	28 Jan 2021 10:02:18
User entered 'No (N)'	System	28 Jan 2021 10:02:18

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-01-28T05:02:14', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'a996930c-0dcb-48da-b837-2e13a5c84b86'	System	28 Jan 2021 10:02:18
User entered '28 Jan 2021 05:02:14'	System	28 Jan 2021 10:02:18



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-02-04T09:21:28', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'c4152abc-ad0d-4316-aa86-cb0f5f44c4e5'	System	04 Feb 2021 14:21:37
User entered 'No (N)'	System	04 Feb 2021 14:21:37

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-02-04T09:21:32', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'c4152abc-ad0d-4316-aa86-cb0f5f44c4e5'	System	04 Feb 2021 14:21:37
User entered 'No (N)'	System	04 Feb 2021 14:21:37

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-02-04T09:21:35', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'c4152abc-ad0d-4316-aa86-cb0f5f44c4e5'	System	04 Feb 2021 14:21:37
User entered '04 Feb 2021 09:21:35'	System	04 Feb 2021 14:21:37

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-02-18T04:29:13', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '4c401463-77a4-4123-a174-d71e30c69b80'	System	18 Feb 2021 09:29:20
User entered 'No (N)'	System	18 Feb 2021 09:29:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-02-18T04:29:16', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '4c401463-77a4-4123-a174-d71e30c69b80'	System	18 Feb 2021 09:29:20
User entered 'No (N)'	System	18 Feb 2021 09:29:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-02-18T04:29:19', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '4c401463-77a4-4123-a174-d71e30c69b80'	System	18 Feb 2021 09:29:20
User entered '18 Feb 2021 04:29:19'	System	18 Feb 2021 09:29:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-02-25T20:18:17-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'eebe3f75-67a4-4ab9-a70c-912ec30a5ddb' User entered 'No (N)'	System	26 Feb 2021 01:18:30
	System	26 Feb 2021 01:18:30

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-02-25T20:18:23-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'eebe3f75-67a4-4ab9-a70c-912ec30a5ddb' User entered 'No (N)'	System	26 Feb 2021 01:18:30

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-02-25T20:18:27-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'eebe3f75-67a4-4ab9-a70c-912ec30a5ddb' User entered '25 Feb 2021 20:18:27'	System	26 Feb 2021 01:18:30
	System	26 Feb 2021 01:18:30

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-03-04T16:45:49-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1f503b2c-f570-476e-a2cc-99a5edea2119'	System	04 Mar 2021 21:46:08
User entered 'No (N)'	System	04 Mar 2021 21:46:08

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-03-04T16:45:58-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1f503b2c-f570-476e-a2cc-99a5edea2119'	System	04 Mar 2021 21:46:08
User entered 'No (N)'	System	04 Mar 2021 21:46:08

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-03-04T16:46:00-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '1f503b2c-f570-476e-a2cc-99a5edea2119'	System	04 Mar 2021 21:46:08
User entered '04 Mar 2021 16:46:00'	System	04 Mar 2021 21:46:08

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-03-18T12:30:32-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ae8e5ffa-a1d8-403e-8d56-c46bfca43f51'	System	18 Mar 2021 16:30:41
User entered 'No (N)'	System	18 Mar 2021 16:30:41

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-03-18T12:30:36-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ae8e5ffa-a1d8-403e-8d56-c46bfca43f51'	System	18 Mar 2021 16:30:41
User entered 'No (N)'	System	18 Mar 2021 16:30:41

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-03-18T12:30:38-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ae8e5ffa-a1d8-403e-8d56-c46bfca43f51'	System	18 Mar 2021 16:30:41
User entered '18 Mar 2021 12:30:38'	System	18 Mar 2021 16:30:41

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[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 (437e61323bb8d485)', Time: '2021-04-17T16:32:40-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '8b356263-a681-4698-99f5-27e608e8042e' User entered 'No (N)'	System	17 Apr 2021 20:32:50
	System	17 Apr 2021 20:32:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

Have you been exposed to someone with 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 (437e61323bb8d485)', Time: '2021-04-17T16:32:44-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '8b356263-a681-4698-99f5-27e608e8042e'	System	17 Apr 2021 20:32:50
User entered 'No (N)'	System	17 Apr 2021 20:32:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-04-17T16:32:47-04:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: '8b356263-a681-4698-99f5-27e608e8042e'	System	17 Apr 2021 20:32:50
User entered '17 Apr 2021 16:32:47'	System	17 Apr 2021 20:32:50

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:30:20



**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:30:20

**US3412200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:30:20
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:30:20

US3412200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:09

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)	26 Apr 2021 08:30:31
User closed query 'Per CDM Review: "Have you eve received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).		19 Apr 2021 08:18:50
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'we reached patient and this has been updated in the con meds. ' (Site from DM).		16 Apr 2021 17:45:36
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).		24 Mar 2021 00:23:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-03-04T16:46:12-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ddbbaec78-5d9c-4712-a523-0ba985450d5d'	System	04 Mar 2021 21:46:41
User entered 'Yes (Y)'	System	04 Mar 2021 21:46:41



US3412200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:09

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-03-04T16:46:24-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ddbaec78-5d9c-4712-a523-0ba985450d5d'	System	04 Mar 2021 21:46:41
User entered 'Yes (Y)'	System	04 Mar 2021 21:46:41

**US3412200**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (437e61323bb8d485)', Time: '2021-03-04T16:46:29-05:00', User OID: 'PatientReportedOutcome (US3412200)', ODM File OID: 'ddbaec78-5d9c-4712-a523-0ba985450d5d' User entered '04 Mar 2021 16:46:29'	System	04 Mar 2021 21:46:41
	System	04 Mar 2021 21:46:41

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:35:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Nov 2020 21:21:52

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:35:50
User entered '4 Nov 2020'	Mason Urban (b) (4)	04 Nov 2020 21:21:52

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:35:50
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Nov 2020 21:21:52

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:35:50
User entered empty.	Mason Urban (b) (4)	04 Nov 2020 21:21:52

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:35:50
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Nov 2020 21:23:57

**US3412200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:11:10
User entered 'I'	System	04 Nov 2020 21:23:57



**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	09 Dec 2020 15:47:09

**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '7 Dec 2020'	Melissa Fuson (b) (4)	09 Dec 2020 15:47:09

**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	09 Dec 2020 15:47:09

**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Melissa Fuson (b) (4)	09 Dec 2020 15:47:09

**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	09 Dec 2020 15:47:17

**US3412200**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User entered 'I'	System	09 Dec 2020 15:47:17

**US3412200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 21:47:05

**US3412200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '6 Jan 2021'	Mason Urban (b) (4)	06 Jan 2021 21:47:05



**US3412200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	06 Jan 2021 21:47:05

**US3412200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Mason Urban (b) (4)	06 Jan 2021 21:47:05

US3412200

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Jan 2021 21:47:31

**US3412200**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User entered 'I'	System	06 Jan 2021 21:47:31

**US3412200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Feb 2021 21:02:53

US3412200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:55:58
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'TRIED TO REACH BUT COULD NOT UNTIL 10 FEB 2021' (Site from System).	Mason Urban (b) (4) (b) (4)	10 Feb 2021 21:03:19
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Feb 2021 21:02:53
User entered '10 Feb 2021'	Mason Urban (b) (4) (b) (4)	10 Feb 2021 21:02:53

**US3412200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	10 Feb 2021 21:02:53

**US3412200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'CALLED BUT VOICE MAIL BOX WAS FULL, COULD NOT REACH ON 5 FEB 2021, 8 FEB 2021, OR 9 FEB 2021'	Mason Urban (b) (4)	10 Feb 2021 21:02:53



**US3412200**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	10 Feb 2021 21:03:41

**US3412200**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:09
User entered 'I'	System	10 Feb 2021 21:03:41

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 19:10:29
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 16:03:08

US3412200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 15:34:54
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'this is the correct date. subject no showed original appointment and site could not get subject in until this date deviation is noted' (Site from System).	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:11:12
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	31 Mar 2021 19:10:29
User entered '23 Mar 2021' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 19:10:29
User entered empty.	Andrea Newlands (b) (4) (b) (4)	30 Mar 2021 16:03:08

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[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 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 19:10:29
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	30 Mar 2021 16:03:08
	(b) (4)	

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered 'VISIT4'	System	30 Mar 2021 16:03:08

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02



**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered empty.	System	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered empty.	System	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02



**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered empty.	System	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered empty.	System	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered empty.	System	30 Mar 2021 16:04:02

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 16:04:05



**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:05

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 19:12:08
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 16:04:07

US3412200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '23 Mar 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 19:12:08
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:07

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '10:46' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 19:12:08
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 16:04:07

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered '23 Mar 2021 10:46'	System	31 Mar 2021 19:12:08
User entered empty.	System	30 Mar 2021 16:04:07

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	30 Mar 2021 16:05:10

**US3412200**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:12
User entered 'I'	System	30 Mar 2021 16:05:10

**US3412200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:38:24



**US3412200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:38:24

**US3412200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:38:24

**US3412200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Called and patient had a full mailbox on 06 APR 2021.'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:38:24

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 15:55:42

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 15:55:42

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	20 Jan 2021 15:55:42

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 15:55:42

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 15:55:55



**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[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 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '0'	Andrea Newlands (b) (4)	18 Mar 2021 16:28:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:10:56

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 15:55:55

US3412200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User closed query 'please complete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:35:27
Query 'please complete' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	18 Mar 2021 16:28:37
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	18 Mar 2021 16:28:33
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:52:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:10:56

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 15:55:55

US3412200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	20 Jan 2021 15:55:55

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	20 Jan 2021 15:55:55

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	20 Jan 2021 15:55:55

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'No (N)'	Mason Urban (b) (4)	20 Jan 2021 15:55:55



**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	20 Jan 2021 15:55:55

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:09**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered empty.	System	20 Jan 2021 15:55:55

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 15:56:08

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 15:56:08

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '11:18'	Mason Urban (b) (4)	20 Jan 2021 15:56:08

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '18 Jan 2021 11:18'	System	20 Jan 2021 15:56:08

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 15:56:18

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 15:56:18



**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '11:17'	Mason Urban (b) (4)	20 Jan 2021 15:56:18

**US3412200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:09**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:00:26
User entered '18 Jan 2021 11:17'	System	20 Jan 2021 15:56:18

US3412200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:31:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:10
User closed query 'Per CDM re-query: Diary Dose 1 Fatigue started on Day 2 per eDiary records. Please update the start date of FATIGUE as appropriate else clarify.' (Site from DM).		26 Apr 2021 19:01:24
Query 'Per CDM re-query: Diary Dose 1 Fatigue started on Day 2 per eDiary records. Please update the start date of FATIGUE as appropriate else clarify.' answered with 'information has been updated' (Site from DM).		19 Apr 2021 13:42:05
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		19 Apr 2021 06:31:07
User opened query 'Per CDM re-query: Diary Dose 1 Fatigue started on Day 2 per eDiary records. Please update the start date of FATIGUE as appropriate else clarify.' (Site from DM).		19 Apr 2021 06:31:05
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		19 Apr 2021 06:29:54
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	(b) (4) 16 Apr 2021 14:44:53

US3412200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:31:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Apr 2021 14:44:49
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 4; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 13:43:18
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		21 Mar 2021 13:43:12
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 13:21:14
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:41:53

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 13:25:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 13:25:48
	(b) (4)	
Data point term sent to Coder	System	19 Feb 2021 13:25:19
User entered 'worsening depression'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '20 Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 13:24:29

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Apr 2021 19:13:57
Signature has been broken.	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Per response "this event has not resolved it worsened into severe depression SAE". An End date is present. Please review and update or reconcile. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:35:33
Query 'Per CDM RQ: Per response "this event has not resolved it worsened into severe depression SAE". An End date is present. Please review and update or reconcile. ' answered with 'this has been updated per query' (Site from DM).	Steven Anderson (b) (4)	26 Apr 2021 19:14:18
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	26 Apr 2021 19:13:57
User opened query 'Per CDM RQ: Per response "this event has not resolved it worsened into severe depression SAE". An End date is present. Please review and update or reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 16:44:10
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	25 Apr 2021 16:38:55
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'this event has not resolved it worsened into severe depression SAE' (Site from System).	Steven Anderson (b) (4)	22 Apr 2021 13:38:32
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	22 Apr 2021 13:37:14
Signature has been broken.	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
User entered '06 Apr 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Please consider if this AE should end due to SAE of severe depression and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 21:37:14
Query 'Please consider if this AE should end due to SAE of severe depression and update as appropriate' answered with 'site put an end date due to this condition worsening and becoming an SAE' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	22 Apr 2021 13:39:08
User opened query 'Please consider if this AE should end due to SAE of severe depression and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:13:28
User signature succeeded.	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:35:02
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 13:24:29

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 13:24:29

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'None (NONE)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'I'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

US3412200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:09

[Outcome](#)

Audit	User	Time (GMT)
Signature has been broken.	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4)	22 Apr 2021 13:37:14
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:35:02
	(b) (4)	
User entered 'subject reported a worsening of depression ~20Sep2020. subject was started on remeron 7.5mg per psychiatrist & increased to 15mg on 02feb2021 due to persistent symptoms. subject reports improvement in depressed mood since start of remeron. denies suicidal ideation/intention.'	Andrea Newlands (b) (4)	19 Feb 2021 13:24:29
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 13:24:29

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 13:24:29

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:25:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:18
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered	(b) (4)	15 Apr 2021 16:16:32
'USA-US061-2021-mRNA-1273-P301000018'	System	15 Apr 2021 16:16:32
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 16:16:32

US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:28:59
Data point term sent to Coder	System	14 Apr 2021 20:28:12
User entered 'Severe depression'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:51:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:01:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:36
User closed query 'Per narrative start date should be 06 Apr 2021' (Site from CRA).	(b) (4)	21 Apr 2021 14:48:56
Query 'Per narrative start date should be 06 Apr 2021' answered with 'this date has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 13:42:28
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 13:41:29
User entered '06 Apr 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 13:41:29
User opened query 'Per narrative start date should be 06 Apr 2021' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 20:40:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '14 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:02:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:27:12



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:44:25
User signature succeeded.	Richard Powell (b) (4)	21 Apr 2021 15:03:33
User entered empty.	(b) (4)	16 Apr 2021 13:31:17
	Steven Anderson (b) (4)	14 Apr 2021 20:27:12
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:44:07
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).		22 Apr 2021 14:36:55
User entered empty.	System	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:03:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:04:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:04:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:04:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:04:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'I'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '06 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '14 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:05:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:06:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:06:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:06:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:06:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:07:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:07:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:07:43
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Steven Anderson (b) (4)	14 Apr 2021 20:27:12
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'I'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:08:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

[Outcome](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:36:43
User signature succeeded.	Richard Powell (b) (4)	21 Apr 2021 15:08:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Steven Anderson (b) (4)	16 Apr 2021 13:31:17 14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:08:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:27:12

US3412200

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per report of "1 injection" for Botox conmed, could you confirm that the subject only received the 1 injection, and that use of this product is not ongoing? Thank you! ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 17:31:51
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).		22 Apr 2021 14:37:06
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).		22 Apr 2021 14:36:38
DataPoint Verified.		21 Apr 2021 15:09:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Subject notified our site at 3:45 pm on 14-apr-2021 of her hospitalization on 060apr-2021 to 14-apr-2021 for sever depression and PTSD. SSubject was prescribed conmed zyprexa 5mg to start as needed on 06-apr-2021. Subject will start daily out patient therapy on 15-apr-2021'	(b) (4) Steven Anderson (b) (4)	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 20:27:12



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 20:27:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:25:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered	(b) (4)	
'USA-US061-2021-mRNA-1273-P301000018'	(b) (4), (b) (6)	15 Apr 2021 16:16:52

US3412200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 20:30:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:30:00
Data point term sent to Coder	System	14 Apr 2021 20:29:18
User entered 'Post traumatic stress disorder'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '06 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
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.	(b) (4), (b) (6)	22 Apr 2021 14:38:55
' (Site from Safety).		
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'I'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '06 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '14 Apr 2021'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '1'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Outcome](#)

Audit	User	Time (GMT)
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)	22 Apr 2021 14:38:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Steven Anderson (b) (4)	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	14 Apr 2021 20:28:34
	(b) (4)	

US3412200

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please specify the trauma that the subject had underwent. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 18:30:55
Query 'PV Query: Please specify the trauma that the subject had underwent. ' answered with 'subject stated this was personal and she did not want to divulge this information. site will not pursue as it was prior to the study.' (Site from Safety).	Steven Anderson (b) (4)	26 Apr 2021 19:16:03
User opened query 'PV Query: Please specify the trauma that the subject had underwent. ' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 14:38:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Subject notified our site at 3:45 pm on 14-apr-2021 of her hospitalization on 060apr-2021 to 14-apr-2021 for sever depression and PTSD. Subject was prescribed conmed zyprexa 5mg to start as needed on 06-apr-2021. Subject will start daily out patient therapy on 15-apr-2021'	Steven Anderson (b) (4)	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 20:28:34

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12

US3412200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:31:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 14:56:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 14:56:42
Data point term sent to Coder	System	16 Apr 2021 14:55:23
User entered 'fatigue'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

US3412200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:31:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:36:11
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Apr 2021 19:16:37
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:58:17
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 18:16:13
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

US3412200

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:31:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
Signature has been broken.		19 Apr 2021 13:41:56
User entered '12 Aug 2020' reason for change: Data Entry Error		19 Apr 2021 13:41:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	16 Apr 2021 14:55:39
User entered '14 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Apr 2021 14:55:39
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	16 Apr 2021 14:55:19
User entered '14 Aug 2021'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 17:37:40
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 17:37:40
User entered '00:00' reason for change: Data Entry Error		20 Apr 2021 17:37:40
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 13:41:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User entered '12 Aug 2020 00:00'	System	20 Apr 2021 17:37:40
User entered empty.	System	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4)	16 Apr 2021 14:55:19
	Andrea Newlands (b) (4)	
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '18 Aug 2020' reason for change: Data Entry Error	System	16 Apr 2021 14:55:39
User opened query 'Future date has been entered. Please correct.' (Site from System).	Andrea Newlands (b) (4)	16 Apr 2021 14:55:39
User entered '18 Aug 2021'	(b) (4)	
	System	16 Apr 2021 14:55:19
	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 17:37:40
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 17:37:40
User entered '00:00' reason for change: Data Entry Error		20 Apr 2021 17:37:40
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 13:41:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User entered '18 Aug 2020 00:00'	System	20 Apr 2021 17:37:40
User entered empty.	System	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	16 Apr 2021 14:55:19
	Andrea Newlands (b) (4)	
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
Signature has been broken.	Steven Anderson (b) (4)	26 Apr 2021 19:16:28
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Steven Anderson (b) (4)	26 Apr 2021 19:16:28
	(b) (4)	
	Richard Powell (b) (4)	16 Apr 2021 18:16:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'None (NONE)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'I'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User entered '0'	System	16 Apr 2021 14:55:19



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12
User entered '0'	System	16 Apr 2021 14:55:19

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:12

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17

US3412200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 14:58:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 14:58:50
Data point term sent to Coder	System	16 Apr 2021 14:57:26
User entered 'headache'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

US3412200

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User closed query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).		29 Apr 2021 08:36:17
Query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Apr 2021 19:16:58
User opened query 'Per MM: This event is captured as a solicited adverse reaction, so please review the relationship to the IP and update, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:58:47
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 18:16:13
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '14 Aug 2020'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User entered empty.	System	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '18 Aug 2020'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User entered empty.	System	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4)	16 Apr 2021 14:57:20
	Andrea Newlands (b) (4)	
	(b) (4)	



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	16 Apr 2021 14:57:20
	Andrea Newlands (b) (4)	
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	16 Apr 2021 14:57:20
	Andrea Newlands (b) (4)	
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
Signature has been broken.	Steven Anderson (b) (4)	26 Apr 2021 19:16:51
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Steven Anderson (b) (4)	26 Apr 2021 19:16:51
	(b) (4)	
	Richard Powell (b) (4)	16 Apr 2021 18:16:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'None (NONE)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'I'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20



**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) Andrea Newlands (b) (4)	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4)	16 Apr 2021 14:57:20
	Andrea Newlands (b) (4)	
	(b) (4)	

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User entered '0'	System	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17
User entered '0'	System	16 Apr 2021 14:57:20

**US3412200**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:41:17



US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Sep 2020 14:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:44:43
Data point term sent to Coder	System	23 Sep 2020 14:44:00
User entered 'wellbutrin'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:43:06



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'anxiety/depression'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '300'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'mg (mg)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:43:06

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:06
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:43:06

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:43:06



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:43:06

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:08:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:44:43
Data point term sent to Coder	System	23 Sep 2020 14:44:03
User entered 'duloxetine'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'anxiety/depression'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '40'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'un UNK 2019'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	23 Sep 2020 14:45:03
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 14:45:03
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:43:38



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User entered '1'	System	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User entered '1'	System	23 Sep 2020 14:43:38

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:51
User entered '804 (804)'	System	23 Sep 2020 14:43:38

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 14:45:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:45:44
Data point term sent to Coder	System	23 Sep 2020 14:45:17
User entered 'clonazepam'	Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'anxiety/depression'	(b) (4) Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0.5'	(b) (4) Jacob sekinger (b) (4)	23 Sep 2020 14:44:21

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4) Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:44:21



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	(b) (4) Jacob sekinger (b) (4)	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'un UNK 2018'	(b) (4) Jacob sekinger (b) (4) (b) (4)	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered '0'	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered empty.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:44:21
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:44:21

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 14:44:21

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:21:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:21:11
Data point term sent to Coder	System	07 Dec 2020 19:19:48
User entered 'DULOXETINE'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4)	
	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41
	(b) (4)	

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'ANXIETY / DEPRESSION'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '50'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41
	(b) (4)	

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41
	(b) (4)	

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41
	(b) (4)	

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'UN UNK 2019'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '26 Aug 2020'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Melissa Fuson (b) (4)	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User entered '1'	System	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User entered '1'	System	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:25:57
User entered '804 (804)'	System	07 Dec 2020 19:19:42
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	07 Dec 2020 19:15:22
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	23 Sep 2020 14:44:41

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
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)	07 Dec 2020 19:22:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:22:45
Data point term sent to Coder	System	07 Dec 2020 19:21:50
User entered 'ADVIL'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 10:53:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'did not meet criteria' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 20:45:30

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:20:01
User entered 'HEADACHE'	Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '200'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:21:27



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '15 Aug 2020'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '17 Aug 2020'	(b) (4) Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User entered '1'	System	07 Dec 2020 19:21:27



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User entered '1'	System	07 Dec 2020 19:21:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:01
User entered '804 (804)'	System	07 Dec 2020 19:21:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
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)	07 Dec 2020 19:23:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:23:47
Data point term sent to Coder	System	07 Dec 2020 19:22:51
User entered 'INFLUENZA VACCINE'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'GENERAL HEALTH'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0.5'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mL (mL)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '14 Oct 2020'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '14 Oct 2020'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User entered empty.	System	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User entered empty.	System	07 Dec 2020 19:22:30

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:05
User entered empty.	System	07 Dec 2020 19:22:30

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 19:25:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 19:25:04
Data point term sent to Coder User entered 'REMERON'	System Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:23:52 07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:22:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 13:24:44
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:09:06
User entered 'DEPRESSION'	Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '7.5'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '21 Oct 2020'	(b) (4) Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 13:20:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:30:55
User entered '02 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 13:20:31
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Melissa Fuson (b) (4)	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User entered '1'	System	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User entered '1'	System	07 Dec 2020 19:23:28

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:09
User entered '804 (804)'	System	07 Dec 2020 19:23:28

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 13:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 13:21:48
Data point term sent to Coder User entered 'remeron'	System Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 13:21:17 19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07
	(b) (4)	



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'depression'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '15'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07
	(b) (4)	

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4)	19 Feb 2021 13:21:07





**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:31:24
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '18 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:31:24
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User entered '1'	System	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User entered '1'	System	19 Feb 2021 13:21:07

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:26:14
User entered '804 (804)'	System	19 Feb 2021 13:21:07



US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 18:22:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 18:22:21
Data point term sent to Coder	System	12 Apr 2021 17:32:55
User entered 'Remeron'	(b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'worsening depression'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '30'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

US3412200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 17:32:26



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 17:32:26

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 17:32:26

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 18:22:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 18:22:35
Data point term sent to Coder	System	12 Apr 2021 17:35:59
User entered 'clonazepam'	(b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'DEPRESSION/anxiety' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 17:35:53
User entered 'depression'	(b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'one tablet in the morning in addition to 1/2 tablet in afternoon'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'un Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 17:35:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 17:35:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:35:53
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Apr 2021 17:35:27
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:35:27

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:35:27

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 15:09:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 15:09:50
Data point term sent to Coder	System	16 Apr 2021 15:08:49
User entered 'Zyprexa'	(b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '5'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58



US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '6 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:07:58

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 15:07:58

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 17:46:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:46:50
Data point term sent to Coder	System	16 Apr 2021 17:45:44
User entered 'Botox'	(b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Cosmetic'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'One injection'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'One injection per visit'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'every six months'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

US3412200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02



**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:16:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:45:02

**US3412200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:45:02



US3412200

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:31:09**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:38:50
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	23 Sep 2020 14:45:11
	(b) (4)	

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'USA-US061-2021-MRNA-1273-P301000018'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32



**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Richard'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Powell'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'OH'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'US'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 14:26:13
User entered '1'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'USA-US061-2021-MRNA-1273-P301000018'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32



**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Richard'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Powell'	System	15 Apr 2021 16:16:32



**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'OH'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'US'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 14:26:13
User entered '1'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:31:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
User entered '15/Apr/2021 12:17'	(b) (4) System	15 Apr 2021 16:17:14

US3412200

Folder: SAE USA-US061-2021-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'I'		15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'USA-US061-2021-MRNA-1273-P301000018'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32



**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Yes (Y)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'No (N)'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Richard'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'Powell'	System	15 Apr 2021 16:16:32

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'OH'	System	15 Apr 2021 16:16:32



**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:13:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:39:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:17:18
User entered 'US'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 14:26:13
User entered '1'	System	15 Apr 2021 16:17:14

**US3412200**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000018**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:31:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:49
User entered '22/Apr/2021 10:26'	(b) (4) System	22 Apr 2021 14:26:13

US3412200

Folder: SAE USA-US061-2021-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:41:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:26:13