

US3352200 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:39:36

All time stamps listed in this document are displayed in GMT

US3352200

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

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Participant ID

US3352200

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

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US3352200

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	22 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	36
Age Units	YEARS
Age (Derived)	36
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Condition	NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Condition	RIGHT INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Condition	RIGHT INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Condition	C SECTION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 12:10
Height (xxx.x)	154.0 cm
Weight (xxx.x)	65.9 kg
BMI (xxx.x)	27.78715 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 28 Apr 2021 13:10:03

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Date of assessment (dd MMM yyyy) 22 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) 28 Apr 2021 13:10:03

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	22 AUG 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)	



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Apr 2021 13:10:03

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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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) 28 Apr 2021 13:10:03

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	True
<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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	22 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107476

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 13:10:03

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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)	22 AUG 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 12:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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)	22 AUG 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:19
Temperature (xxx.x)	36.8 C
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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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) 28 Apr 2021 13:10:03

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Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 13:19 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 13:19

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) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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

Collection date (dd MMM yyyy)	22 AUG 2020
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Collection time (00:00-23:59)	12:34 (24 HR)
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Collection date and time (derived)	22 AUG 2020 12:34
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:27	22 AUG 2020 12:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

22 AUG 2020 13:56

PC Open Date & Time

22 AUG 2020 13:39

PC Close Date & Time

22 AUG 2020 16:09

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.2 °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	22 AUG 2020 21:55
PC Open Date & Time	22 AUG 2020 17:04
PC Close Date & Time	23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	95.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 AUG 2020 23:54
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

95.5 °F

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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

24 AUG 2020 20:41

---

PC Open Date & Time

24 AUG 2020 12:00

---

PC Close Date & Time

25 AUG 2020 11:59

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US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**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

25 AUG 2020 22:37

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**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

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**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

27 AUG 2020 22:10

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 00:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 13:54

PC Open Date & Time

22 AUG 2020 13:39

PC Close Date & Time

22 AUG 2020 16:09

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 21:55

PC Open Date & Time

22 AUG 2020 17:04

PC Close Date & Time

23 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**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

23 AUG 2020 23:50

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**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

24 AUG 2020 20:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**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

25 AUG 2020 22:35

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**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

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**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

27 AUG 2020 22:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**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

29 AUG 2020 00:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**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 ☐

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 13:55
PC Open Date & Time	22 AUG 2020 13:39
PC Close Date & Time	22 AUG 2020 16:09

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**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 ☐



US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 21:56
PC Open Date & Time	22 AUG 2020 17:04
PC Close Date & Time	23 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 23:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

51 of 1804

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 20:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 ☒

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 22:35
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 ☐



US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 ☒

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 ☒

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 00:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3352200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3352200

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	19 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
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US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 SEP 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 13:13
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 SEP 2020
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	19 SEP 2020 14:53
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3352200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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.*

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 19 SEP 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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



US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 SEP 2020

What was the treatment time? (00:00-23:59) 14:23 (24 HR)

Treatment Date and Time (derived) 19 SEP 2020 14:23

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

US3352200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 SEP 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

19 SEP 2020 13:40

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Collection date (dd MMM yyyy)			19 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:33	19 SEP 2020 13:33
Nasopharyngeal Swab 2	No		

US3352200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**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

19 SEP 2020 14:59

PC Open Date & Time

19 SEP 2020 14:43

PC Close Date & Time

19 SEP 2020 17:13

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

PC Time Stamp	19 SEP 2020 22:20
PC Open Date & Time	19 SEP 2020 18:08
PC Close Date & Time	20 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**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

100.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 SEP 2020 20:27

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

21 SEP 2020 22:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

22 SEP 2020 23:50

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

23 SEP 2020 21:40

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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**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.

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

24 SEP 2020 23:04

---

PC Open Date & Time

24 SEP 2020 12:00

---

PC Close Date & Time

25 SEP 2020 11:59

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US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**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.

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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

25 SEP 2020 21:41

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 15:00

PC Open Date & Time

19 SEP 2020 14:43

PC Close Date & Time

19 SEP 2020 17:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 22:19

PC Open Date & Time

19 SEP 2020 18:08

PC Close Date & Time

20 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

20

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

20 SEP 2020 20:26

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**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 ☐

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

15

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)**

10

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

21 SEP 2020 22:36

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

5

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

22 SEP 2020 23:51

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**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

24 SEP 2020 23:04

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**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

25 SEP 2020 21:41

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**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 ☐

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 15:00
PC Open Date & Time	19 SEP 2020 14:43
PC Close Date & Time	19 SEP 2020 17:13

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**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 ☐

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 22:20
PC Open Date & Time	19 SEP 2020 18:08
PC Close Date & Time	20 SEP 2020 11:59



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 ☒

PRODUCTION RELEASE (v12.003

96 of 1804

EAB) (1725)

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:27
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1804

EAB) (1725)

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 22:37
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

100 of 1804

EAB) (1725)

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:51
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 ☒

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:41
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 ☒

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 23:04
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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

106 of 1804

EAB) (1725)

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 21:41
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 9

Select one response below to indicate the level of your

**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 ☐

PC Time stamp

27 SEP 2020 23:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:39:36

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3352200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:39:36

<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	27 SEP 2020 23:12
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3352200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	15 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:13
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3352200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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.*

US3352200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

11:39 (24 HR)

Collection date and time (derived)

15 OCT 2020 11:39

US3352200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 OCT 2020 15:15:35
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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°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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 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	08 NOV 2020 20:55:06
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 18:27:54

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 14:22:00
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

03 DEC 2020 18:44:31

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 17:44:42

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 15:09:05
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 16:56:19
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

29 DEC 2020 08:35:12

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 08:40:11

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 12:58:41

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 14:01:22

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

27 JAN 2021 09:59:53

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 17:19:17
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

11 FEB 2021 21:15:41

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 13:31:17

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 10:13:31

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 17:01:01
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

08 MAR 2021 06:37:04

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

16 MAR 2021 18:12:53

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 12:00:30

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

30 MAR 2021 16:51:08

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 17:09:50

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 15:48:25
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 18:02:07

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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

29 APR 2021 17:59:21

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 08:32:40

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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14 MAY 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 <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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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="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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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="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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 SEP 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 <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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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="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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2021 23:59
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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59
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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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04 FEB 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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11 FEB 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 <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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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18 FEB 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 <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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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="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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

25 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

15 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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="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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59



US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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14 OCT 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

**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°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 ☐

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2022 23:59

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US3352200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3352200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:39:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:41:34

US3352200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3352200

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	18 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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US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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) \_\_\_\_\_

US3352200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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.*



US3352200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

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

Collection date (dd MMM yyyy)	18 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:02 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	18 MAR 2021 09:02
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US3352200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:52

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3352200

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3352200**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3352200**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352200

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:36

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>

**US3352200**

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

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

**Generated On: 11 Aug 2021 22:39:36**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3352200

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3352200

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Date of updated informed consent (dd MMM yyyy) 26 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) 26 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 \_\_\_\_\_

US3352200

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

10:14 (24 HR)

Collection date and time (derived)

26 JAN 2021 10:14

US3352200

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00 - 23:59)

10:09

Collection Date and Time (derived)

26 JAN 2021 10:09

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Visit Date	26 JAN 2021
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Please check all assessments that apply for this visit

Physical Exam	False
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Vital Signs	False
-------------	-------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	True
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US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	26 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3352200

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

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Did the participant experience any adverse events?

Yes ☐

No ☒

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If Yes, enter details on the Adverse Events form.

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

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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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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 1804

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

	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)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

	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)	23 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) 23 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

	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)		20 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

	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)		20 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

Name of Medication ONE A DAY

Prophylaxis Yes ☒  
No ☐

Indication MULTIVITAMIN

Dose per administration 1

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

If dose unit is Other, specify CAP

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:10:02

Generated On: 11 Aug 2021 22:39:36

	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)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 13:10:03

Generated On: 11 Aug 2021 22:39:36

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3352200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:36

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

US3352200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:36

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 ☐

Audit

US3352200 (Prod: Research Centers of America - ERG)

**US3352200**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:39:36**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'US3352200'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 15:44:12

US3352200

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:19:02



US3352200

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 15:44:13

US3352200

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Aug 2020 18:19:02

**US3352200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'SCRN'	System	22 Aug 2020 18:19:02

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 15:44:14

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '36'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

**US3352200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:39:36**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'YEARS'	System	22 Aug 2020 18:19:39

**US3352200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:39:36**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '36'	System	22 Aug 2020 17:51:42

**US3352200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:39:36**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Female (F)'	(b) (4), (b) (6)	22 Aug 2020 18:19:39



US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'I'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

**US3352200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:39:36**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:19:39



US3352200

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

**US3352200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:39:36**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:19:39

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:51:42

**US3352200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Aug 2020'	System	22 Aug 2020 17:51:42

**US3352200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2020'	System	22 Aug 2020 17:51:42

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	22 Aug 2020 17:51:42

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:51:42

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:51:42



US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:51:42

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 17:51:42

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 15:44:13

US3352200

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'I'	System	22 Aug 2020 17:51:47

US3352200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:51:47

US3352200

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:39:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:20:07

US3352200

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as SOC: Nervous system disorders, HLGHT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:21:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:21:22
Data point term sent to Coder	System	22 Aug 2020 18:20:45
User entered 'MIGRAINES'	(b) (4), (b) (6)	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'UN UNK 2005'	(b) (4), (b) (6)	22 Aug 2020 18:20:25



**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:20:25

US3352200

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2005'	System	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2005'	System	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered empty.	System	22 Aug 2020 18:20:25

**US3352200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered empty.	System	22 Aug 2020 18:20:25



US3352200

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:22:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:22:23
Data point term sent to Coder	System	22 Aug 2020 18:21:48
User entered 'NEARSIGHTED'	(b) (4), (b) (6)	22 Aug 2020 18:21:11

US3352200

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'UN UNK 2005'	(b) (4), (b) (6)	22 Aug 2020 18:21:11

**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:21:11

US3352200

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:21:11

**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:21:11

US3352200

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:21:11

**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2005'	System	22 Aug 2020 18:21:11

**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2005'	System	22 Aug 2020 18:21:11



**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered empty.	System	22 Aug 2020 18:21:11

**US3352200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered empty.	System	22 Aug 2020 18:21:11

US3352200

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Right inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 07:25:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 07:25:30
Data point term sent to Coder	System	22 Aug 2020 18:21:48
User entered 'right inguinal hernia'	(b) (4), (b) (6)	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'UN UNK 2011'	(b) (4), (b) (6)	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:21:46

US3352200

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'UN UNK 2011'	(b) (4), (b) (6)	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:21:46



**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2011'	System	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2011'	System	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2011'	System	22 Aug 2020 18:21:46

**US3352200**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2011'	System	22 Aug 2020 18:21:46

US3352200

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
Data point term sent to Coder	System	22 Aug 2020 18:23:49
User entered 'right inguinal hernia REPAIR'	(b) (4), (b) (6)	22 Aug 2020 18:22:50

US3352200

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'un UNK 2011'	(b) (4), (b) (6)	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:22:50



**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'un UNK 2011'	(b) (4), (b) (6)	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2011'	System	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2011'	System	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2011'	System	22 Aug 2020 18:22:50

**US3352200**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2011'	System	22 Aug 2020 18:22:50

US3352200

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 18:24:23
Data point term sent to Coder	System	22 Aug 2020 18:23:51
User entered 'c section'	(b) (4), (b) (6)	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'un UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 18:23:13



**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:23:13

US3352200

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'un UNK 2018'	(b) (4), (b) (6)	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2018'	System	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2018'	System	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'Jan 2018'	System	22 Aug 2020 18:23:13

**US3352200**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '2018'	System	22 Aug 2020 18:23:13



US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:24:00

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '12:10'	(b) (4), (b) (6)	22 Aug 2020 18:24:00

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered '22 Aug 2020 12:10'	System	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '154.0' cm	(b) (4), (b) (6)	22 Aug 2020 18:24:00
DataPoint set to visible.	System	22 Aug 2020 17:51:47

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '65.9' kg	(b) (4), (b) (6)	22 Aug 2020 18:24:00
DataPoint set to visible.	System	22 Aug 2020 17:51:47

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
Amendment Manager: User entered '27.78715'	System	17 Sep 2020 00:19:56
User entered '27.8'	System	22 Aug 2020 18:24:00
DataPoint set to visible.	System	22 Aug 2020 17:51:47

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'kg/m2'	System	22 Aug 2020 18:24:00
DataPoint set to visible.	System	22 Aug 2020 17:51:47



US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'bpm'	System	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'breaths/min'	System	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:24:00



US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'mmHg'	System	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:24:00

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered 'mmHg'	System	22 Aug 2020 18:24:00

US3352200

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35

**US3352200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35

US3352200

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:24:10

US3352200

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:24:10

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:24:48



US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:36

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:48

**US3352200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:39:36**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:24:48

US3352200

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:24:58



US3352200

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:24:58

US3352200

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Aug 2020 18:24:58

**US3352200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Aug 2020 18:24:58

US3352200

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:15:32
Query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' answered with 'data updated' (Site from DM).	Matthew Muniz (b) (4)	05 Oct 2020 12:53:23
User entered 'No (N)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Oct 2020 12:53:10
User opened query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:18:17
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:58

US3352200

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:58

**US3352200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:24:58

**US3352200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User entered empty.	System	22 Aug 2020 18:24:58

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44



US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44



US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

**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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'I'	(b) (4), (b) (6)	22 Aug 2020 18:25:44



US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

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)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:11:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:25:44

US3352200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:26:00

US3352200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:26:00

US3352200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Aug 2020 18:26:00

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'VISIT1'	System	22 Aug 2020 18:26:00



US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:44:13

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '107476'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:44:13

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 16:44:13

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

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)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:26:15

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

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)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:26:15

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:39:36**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:26:15

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:26:15

US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:26:15



US3352200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:36

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:19:08
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	05 Nov 2020 19:49:26
User entered 'No (N)'	Matthew Muniz (b) (4)	05 Nov 2020 19:49:17
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:08:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:18:52

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:27:49



US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '12:10'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered '22 Aug 2020 12:10'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Aug 2020 18:27:56
User entered '36.8' C reason for change: Data Entry Error	(b) (4), (b) (6)	22 Aug 2020 18:27:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Aug 2020 18:27:49
User entered '36.8' (non-conformant).	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '64'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'bpm'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '14'	(b) (4), (b) (6)	22 Aug 2020 18:27:49



US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'breaths/min'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '106'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'mmHg'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '72'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'mmHg'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49



US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:13:49
Query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' answered with 'deviation to be filed data correct as entered ' (Site from DM).	Matthew Muniz (b) (4)	07 Oct 2020 18:58:18
User opened query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:54:13
Query 'Vital signs ' canceled (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:54:05
User opened query 'Vital signs ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:54:02
User entered '13:19'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered '22 Aug 2020 13:19'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '36.8' C	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '66'	(b) (4), (b) (6)	22 Aug 2020 18:27:49



US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'bpm'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '13'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'breaths/min'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '112'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'mmHg'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '73'	(b) (4), (b) (6)	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'mmHg'	System	22 Aug 2020 18:27:49

US3352200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:28:00



US3352200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:28:00

US3352200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:38:33
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Corrected' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 22:17:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:17:14
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:15:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:28:08

US3352200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:17:14
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:28:08

US3352200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:17:14
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Aug 2020 18:28:08

US3352200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:17:14
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Aug 2020 18:28:08

US3352200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:28:08

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:28:08

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:28:08



**US3352200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered empty.	System	22 Aug 2020 18:28:08

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

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)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '13:19'	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered '22 Aug 2020 13:19'	System	22 Aug 2020 17:52:18



US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'ONCE'	System	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 17:52:18

US3352200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:28:53

US3352200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:28:53

US3352200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '12:34'	(b) (4), (b) (6)	22 Aug 2020 18:28:53

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered '22 Aug 2020 12:34'	System	22 Aug 2020 18:28:53

US3352200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:29:06



**US3352200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Aug 2020 18:29:06

US3352200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:29:06

US3352200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '12:27'	(b) (4), (b) (6)	22 Aug 2020 18:29:06

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered '22 Aug 2020 12:27'	System	22 Aug 2020 18:29:06

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Aug 2020 18:29:06

US3352200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:29:06

US3352200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:29:06

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered empty.	System	22 Aug 2020 18:29:06



US3352200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:29:10

**US3352200**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:38:12
User entered 'I'	System	22 Aug 2020 18:29:10

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:55:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1b65f082-ee0c-4c18-b414-443ad427fa9c' User entered 'Yes (Y)'	System	22 Aug 2020 17:56:48
	System	22 Aug 2020 17:56:48

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:56:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1b65f082-ee0c-4c18-b414-443ad427fa9c' User entered '97.5'	System	22 Aug 2020 17:56:48
	System	22 Aug 2020 17:56:48

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:56:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1b65f082-ee0c-4c18-b414-443ad427fa9c'	System	22 Aug 2020 17:56:48
User entered 'No (N)'	System	22 Aug 2020 17:56:48

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:56:45', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1b65f082-ee0c-4c18-b414-443ad427fa9c' User entered '22 Aug 2020 13:56'	System	22 Aug 2020 17:56:48
	System	22 Aug 2020 17:56:48

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 13:39'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 16:09'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76bd96a9-db1d-4f51-93ec-efe9bf84182c' User entered 'Yes (Y)'	System	23 Aug 2020 01:55:55
	System	23 Aug 2020 01:55:55

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:47', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76bd96a9-db1d-4f51-93ec-efe9bf84182c' User entered '96.2'	System	23 Aug 2020 01:55:55
	System	23 Aug 2020 01:55:55

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:50', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76bd96a9-db1d-4f51-93ec-efe9bf84182c' User entered 'No (N)'	System	23 Aug 2020 01:55:55
	System	23 Aug 2020 01:55:55

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76bd96a9-db1d-4f51-93ec-efe9bf84182c' User entered '22 Aug 2020 21:55'	System	23 Aug 2020 01:55:55
	System	23 Aug 2020 01:55:55

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 17:04'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 2'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered 'Yes (Y)'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:54:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered '95.4'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:54:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered 'Yes (Y)'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:14:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:54:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered '1'	Wanda Delgado (b) (4)	14 Nov 2020 14:09:23
	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:54:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered '0'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:54:30', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '96f26217-3e30-4ba1-abc6-d336defb617a' User entered '23 Aug 2020 23:54'	System	24 Aug 2020 03:54:38
	System	24 Aug 2020 03:54:38

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 3'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3707d857-31ee-4b50-930e-3ed7466afeb'	System	25 Aug 2020 00:41:41
User entered 'Yes (Y)'	System	25 Aug 2020 00:41:41

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3707d857-31ee-4b50-930e-3ed7466afeb' User entered '95.5'	System	25 Aug 2020 00:41:41
	System	25 Aug 2020 00:41:41

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:35', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3707d857-31ee-4b50-930e-3ed7466afeeb'	System	25 Aug 2020 00:41:41
User entered 'No (N)'	System	25 Aug 2020 00:41:41

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3707d857-31ee-4b50-930e-3ed7466afeb'	System	25 Aug 2020 00:41:41
User entered '24 Aug 2020 20:41'	System	25 Aug 2020 00:41:41

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 4'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'faa17c13-5ab7-4ac4-a8ab-689de0448acb' User entered 'Yes (Y)'	System	26 Aug 2020 02:37:20
	System	26 Aug 2020 02:37:20

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:37:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'faa17c13-5ab7-4ac4-a8ab-689de0448acb' User entered '97.3'	System	26 Aug 2020 02:37:20
	System	26 Aug 2020 02:37:20

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:37:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'faa17c13-5ab7-4ac4-a8ab-689de0448acb'	System	26 Aug 2020 02:37:20
User entered 'No (N)'	System	26 Aug 2020 02:37:20

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:37:15', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'faa17c13-5ab7-4ac4-a8ab-689de0448acb' User entered '25 Aug 2020 22:37'	System	26 Aug 2020 02:37:20
	System	26 Aug 2020 02:37:20

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 5'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 6'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:10:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '870c2cc3-c823-4e63-923a-f63f23951b23' User entered 'Yes (Y)'	System	28 Aug 2020 02:10:57
	System	28 Aug 2020 02:10:57

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:10:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '870c2cc3-c823-4e63-923a-f63f23951b23' User entered '98.2'	System	28 Aug 2020 02:10:57
	System	28 Aug 2020 02:10:57

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:10:52', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '870c2cc3-c823-4e63-923a-f63f23951b23' User entered 'No (N)'	System	28 Aug 2020 02:10:57
	System	28 Aug 2020 02:10:57

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:10:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '870c2cc3-c823-4e63-923a-f63f23951b23' User entered '27 Aug 2020 22:10'	System	28 Aug 2020 02:10:57
	System	28 Aug 2020 02:10:57

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 7'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ef4ed2ce-8c2c-4b5d-9644-68e58897a2f8'	System	29 Aug 2020 04:08:24
User entered 'Yes (Y)'	System	29 Aug 2020 04:08:24

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:17', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ef4ed2ce-8c2c-4b5d-9644-68e58897a2f8' User entered '96.8'	System	29 Aug 2020 04:08:24
	System	29 Aug 2020 04:08:24

US3352200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:20', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ef4ed2ce-8c2c-4b5d-9644-68e58897a2f8'	System	29 Aug 2020 04:08:24
User entered 'No (N)'	System	29 Aug 2020 04:08:24

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:22', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ef4ed2ce-8c2c-4b5d-9644-68e58897a2f8'	System	29 Aug 2020 04:08:24
User entered '29 Aug 2020 00:08'	System	29 Aug 2020 04:08:24

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:53:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '81d9cf5a-5fbf-4eb5-88dd-b0a8a2f02662'	System	22 Aug 2020 17:54:48
User entered 'None (1)'	System	22 Aug 2020 17:54:48



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '81d9cf5a-5fbf-4eb5-88dd-b0a8a2f02662'	System	22 Aug 2020 17:54:48
User entered 'No (N)'	System	22 Aug 2020 17:54:48

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '81d9cf5a-5fbf-4eb5-88dd-b0a8a2f02662'	System	22 Aug 2020 17:54:48
User entered 'No (N)'	System	22 Aug 2020 17:54:48

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '81d9cf5a-5fbf-4eb5-88dd-b0a8a2f02662'	System	22 Aug 2020 17:54:48
User entered 'None (1)'	System	22 Aug 2020 17:54:48

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:45', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '81d9cf5a-5fbf-4eb5-88dd-b0a8a2f02662'	System	22 Aug 2020 17:54:48
User entered '22 Aug 2020 13:54'	System	22 Aug 2020 17:54:48

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 13:39'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 16:09'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:54:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'db0240a0-906d-4811-ba94-10093aa42de8'	System	23 Aug 2020 01:55:36
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 01:55:36



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'db0240a0-906d-4811-ba94-10093aa42de8'	System	23 Aug 2020 01:55:36
User entered 'No (N)'	System	23 Aug 2020 01:55:36

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'db0240a0-906d-4811-ba94-10093aa42de8' User entered 'No (N)'	System	23 Aug 2020 01:55:36
	System	23 Aug 2020 01:55:36

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'db0240a0-906d-4811-ba94-10093aa42de8'	System	23 Aug 2020 01:55:36
User entered 'None (1)'	System	23 Aug 2020 01:55:36

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'db0240a0-906d-4811-ba94-10093aa42de8' User entered '22 Aug 2020 21:55'	System	23 Aug 2020 01:55:36
	System	23 Aug 2020 01:55:36

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 17:04'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 2'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:50:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c51daa-a3c2-4842-9ae2-f9bbc94486c6'	System	24 Aug 2020 03:50:59
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 03:50:59



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:50:42', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c51daa-a3c2-4842-9ae2-f9bbc94486c6' User entered 'No (N)'	System	24 Aug 2020 03:50:59
	System	24 Aug 2020 03:50:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:50:48', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c51daa-a3c2-4842-9ae2-f9bbc94486c6' User entered 'No (N)'	System	24 Aug 2020 03:50:59
	System	24 Aug 2020 03:50:59

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:50:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c51daa-a3c2-4842-9ae2-f9bbc94486c6' User entered 'None (1)'	System	24 Aug 2020 03:50:59
	System	24 Aug 2020 03:50:59

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:50:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c51daa-a3c2-4842-9ae2-f9bbc94486c6' User entered '23 Aug 2020 23:50'	System	24 Aug 2020 03:50:59
	System	24 Aug 2020 03:50:59

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 3'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'acaa8fb3-63de-46e5-b2e0-3d3ec1a67435'	System	25 Aug 2020 00:41:23
User entered 'None (1)'	System	25 Aug 2020 00:41:23



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'acaa8fb3-63de-46e5-b2e0-3d3ec1a67435'	System	25 Aug 2020 00:41:23
User entered 'No (N)'	System	25 Aug 2020 00:41:23

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'acaa8fb3-63de-46e5-b2e0-3d3ec1a67435'	System	25 Aug 2020 00:41:23
User entered 'No (N)'	System	25 Aug 2020 00:41:23

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'acaa8fb3-63de-46e5-b2e0-3d3ec1a67435'	System	25 Aug 2020 00:41:23
User entered 'None (1)'	System	25 Aug 2020 00:41:23

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:41:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'acaa8fb3-63de-46e5-b2e0-3d3ec1a67435' User entered '24 Aug 2020 20:41'	System	25 Aug 2020 00:41:23
	System	25 Aug 2020 00:41:23

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 4'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:37', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '90c7889b-8a90-4fa8-93db-504723d048a8' User entered 'None (1)'	System	26 Aug 2020 02:35:54
	System	26 Aug 2020 02:35:54



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:40', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '90c7889b-8a90-4fa8-93db-504723d048a8' User entered 'No (N)'	System	26 Aug 2020 02:35:54
	System	26 Aug 2020 02:35:54

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:44', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '90c7889b-8a90-4fa8-93db-504723d048a8' User entered 'No (N)'	System	26 Aug 2020 02:35:54
	System	26 Aug 2020 02:35:54

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '90c7889b-8a90-4fa8-93db-504723d048a8' User entered 'None (1)'	System	26 Aug 2020 02:35:54
	System	26 Aug 2020 02:35:54

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '90c7889b-8a90-4fa8-93db-504723d048a8' User entered '25 Aug 2020 22:35'	System	26 Aug 2020 02:35:54
	System	26 Aug 2020 02:35:54

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 5'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 6'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e5d93a8-d98d-4f7a-b1ed-242cdb34cecc' User entered 'None (1)'	System	28 Aug 2020 02:09:27
	System	28 Aug 2020 02:09:27

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e5d93a8-d98d-4f7a-b1ed-242cdb34cecc' User entered 'No (N)'	System	28 Aug 2020 02:09:27
	System	28 Aug 2020 02:09:27

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:15', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e5d93a8-d98d-4f7a-b1ed-242cdb34cecc' User entered 'No (N)'	System	28 Aug 2020 02:09:27
	System	28 Aug 2020 02:09:27

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:22', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e5d93a8-d98d-4f7a-b1ed-242cdb34cecc' User entered 'None (1)'	System	28 Aug 2020 02:09:27
	System	28 Aug 2020 02:09:27

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e5d93a8-d98d-4f7a-b1ed-242cdb34cecc' User entered '27 Aug 2020 22:09'	System	28 Aug 2020 02:09:27
	System	28 Aug 2020 02:09:27

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 7'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76205495-0145-4878-bb73-52ce5e539dee' User entered 'None (1)'	System	29 Aug 2020 04:08:38
	System	29 Aug 2020 04:08:38

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76205495-0145-4878-bb73-52ce5e539dee' User entered 'No (N)'	System	29 Aug 2020 04:08:38
	System	29 Aug 2020 04:08:38

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:30', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76205495-0145-4878-bb73-52ce5e539dee' User entered 'No (N)'	System	29 Aug 2020 04:08:38
	System	29 Aug 2020 04:08:38

US3352200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76205495-0145-4878-bb73-52ce5e539dee' User entered 'None (1)'	System	29 Aug 2020 04:08:38
	System	29 Aug 2020 04:08:38

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:36', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '76205495-0145-4878-bb73-52ce5e539dee' User entered '29 Aug 2020 00:08'	System	29 Aug 2020 04:08:38
	System	29 Aug 2020 04:08:38

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:52', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:54:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:55:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:55:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'None (0)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:55:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58' User entered 'No (N)'	System	22 Aug 2020 17:55:14
	System	22 Aug 2020 17:55:14



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T13:55:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1cc8a489-9d11-4ae1-931e-067f7dd99c58'	System	22 Aug 2020 17:55:14
User entered '22 Aug 2020 13:55'	System	22 Aug 2020 17:55:14

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 13:39'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 16:09'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:55:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:03', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:05', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:07', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'None (0)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:13', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered 'No (N)'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-22T21:56:15', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '34e7dd81-4045-4e84-b98a-3884f51d0bb1' User entered '22 Aug 2020 21:56'	System	23 Aug 2020 01:56:18
	System	23 Aug 2020 01:56:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Aug 2020 17:04'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 2'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa'	System	24 Aug 2020 03:53:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Aug 2020 03:53:53



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:23', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered 'None (0)'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered 'None (0)'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:30', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered 'No interference with activity (1)'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa'	System	24 Aug 2020 03:53:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 03:53:53

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:45', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered 'None (0)'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered 'No (N)'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-23T23:53:52', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '3a16b05f-8603-4e67-9aea-7bf2717efcfa' User entered '23 Aug 2020 23:53'	System	24 Aug 2020 03:53:53
	System	24 Aug 2020 03:53:53

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 3'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:23', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'None (0)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'None (0)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:27', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'None (0)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:30', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'None (0)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:36', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173'	System	25 Aug 2020 00:40:46
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 00:40:46

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'None (0)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46



US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered 'No (N)'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-24T20:40:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '40c16f46-12f5-419c-88ad-f1b3f4cbb173' User entered '24 Aug 2020 20:40'	System	25 Aug 2020 00:40:46
	System	25 Aug 2020 00:40:46

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 4'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'None (0)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'None (0)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:13', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'None (0)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35



US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:16', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'None (0)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff'	System	26 Aug 2020 02:35:35
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Aug 2020 02:35:35

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'None (0)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered 'No (N)'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-25T22:35:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '93d11ed8-70ac-41c5-9df8-27c9575b43ff' User entered '25 Aug 2020 22:35'	System	26 Aug 2020 02:35:35
	System	26 Aug 2020 02:35:35

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 5'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 6'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:29', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:32', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:36', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56



**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:40', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'None (0)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered 'No (N)'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-27T22:09:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f378f8d8-c909-4291-8132-fd03c5ec5109' User entered '27 Aug 2020 22:09'	System	28 Aug 2020 02:09:56
	System	28 Aug 2020 02:09:56

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 7'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:07:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:07:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10



US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:07:56', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:07:58', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:07:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'None (0)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

US3352200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered 'No (N)'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-08-29T00:08:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c7752038-96a1-4335-a871-d7669fb685f5' User entered '29 Aug 2020 00:08'	System	29 Aug 2020 04:08:10
	System	29 Aug 2020 04:08:10

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 17:52:18

**US3352200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 17:52:18



**US3352200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 16:29:25

US3352200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '29 Aug 2020'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 16:29:25

US3352200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 16:29:25

US3352200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Rosaidaliz Carreira (b) (4)	29 Aug 2020 16:29:25

US3352200

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	29 Aug 2020 16:29:33

**US3352200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:11:05
User entered 'I'	System	29 Aug 2020 16:29:33

**US3352200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 15:34:02

US3352200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '05 Sep 2020'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 15:34:02



US3352200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 15:34:02

**US3352200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Rosaidaliz Carreira (b) (4)	05 Sep 2020 15:34:02

US3352200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	05 Sep 2020 15:33:48

**US3352200**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User entered 'I'	System	05 Sep 2020 15:33:48

**US3352200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 18:57:49

US3352200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '12 Sep 2020'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 18:57:49

US3352200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 18:57:49

**US3352200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Rosaidaliz Carreira (b) (4)	14 Sep 2020 18:57:49



US3352200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	14 Sep 2020 18:57:38

**US3352200**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:57:08
User entered 'I'	System	14 Sep 2020 18:57:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:23:48

US3352200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:23:48

US3352200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	19 Sep 2020 19:23:48

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'VISIT2'	System	19 Sep 2020 19:23:48

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User accepted default value 'Pre-Dose (PREDOSE)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05



US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '13:13'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '19 Sep 2020 13:13'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '36.5' C	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '67'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'bpm'	System	19 Sep 2020 19:30:05



US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '16'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'breaths/min'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '102'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'mmHg'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '68'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'mmHg'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User accepted default value 'Post-Dose (POSTDOSE)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05



US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '14:53'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '19 Sep 2020 14:53'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '36.8' C	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '62'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'bpm'	System	19 Sep 2020 19:30:05



US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '16'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'breaths/min'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '113'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'mmHg'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '77'	Wanda Delgado (b) (4)	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'mmHg'	System	19 Sep 2020 19:30:05

US3352200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	19 Sep 2020 19:24:25
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:10

US3352200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	19 Sep 2020 19:24:25
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:10



US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Urine (URINE)'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Negative (NEGATIVE)'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)'	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

US3352200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	Wanda Delgado (b) (4)	19 Sep 2020 19:24:39

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered empty.	System	19 Sep 2020 19:24:39



US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

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)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'MRNA-1273 OR PLACEBO'	System	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	(b) (4), (b) (6)	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '14:23'	(b) (4), (b) (6)	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '19 Sep 2020 14:23'	System	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Sep 2020 18:41:38



US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'ONCE'	System	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered 'INTRAMUSCULAR'	System	19 Sep 2020 18:41:38

US3352200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:03

US3352200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:03

US3352200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '13:40'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:03

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '19 Sep 2020 13:40'	System	19 Sep 2020 19:28:03

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '19 Sep 2020'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18



US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '13:33'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '19 Sep 2020 13:33'	System	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	Wanda Delgado (b) (4)	19 Sep 2020 19:28:18

**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered empty.	System	19 Sep 2020 19:28:18

US3352200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	19 Sep 2020 19:28:24



**US3352200**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:42:09
User entered '1'	System	19 Sep 2020 19:28:24

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c2a8e46a-2e44-454c-89df-850036242216' User entered 'Yes (Y)'	System	19 Sep 2020 18:59:41
	System	19 Sep 2020 18:59:41

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:30', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c2a8e46a-2e44-454c-89df-850036242216' User entered '98.1'	System	19 Sep 2020 18:59:41
	System	19 Sep 2020 18:59:41

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c2a8e46a-2e44-454c-89df-850036242216' User entered 'No (N)'	System	19 Sep 2020 18:59:41
	System	19 Sep 2020 18:59:41

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:37', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'c2a8e46a-2e44-454c-89df-850036242216' User entered '19 Sep 2020 14:59'	System	19 Sep 2020 18:59:41
	System	19 Sep 2020 18:59:41

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 14:43'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 17:13'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ee866f10-b5db-417c-838c-a7037af430cf' User entered 'Yes (Y)'	System	20 Sep 2020 02:20:52
	System	20 Sep 2020 02:20:52

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ee866f10-b5db-417c-838c-a7037af430cf' User entered '96.5'	System	20 Sep 2020 02:20:52
	System	20 Sep 2020 02:20:52

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ee866f10-b5db-417c-838c-a7037af430cf' User entered 'No (N)'	System	20 Sep 2020 02:20:52
	System	20 Sep 2020 02:20:52

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:47', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ee866f10-b5db-417c-838c-a7037af430cf' User entered '19 Sep 2020 22:20'	System	20 Sep 2020 02:20:52
	System	20 Sep 2020 02:20:52

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 18:08'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 2'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:17', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084' User entered 'Yes (Y)'	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:42', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084' User entered '100.7'	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:45', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084'	System	21 Sep 2020 00:27:57
User entered 'Yes (Y)'	System	21 Sep 2020 00:27:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed ' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 15:14:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084'	Wanda Delgado (b) (4)	14 Nov 2020 14:06:59
User entered '1'	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084' User entered '0'	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f3337c54-42fa-42e6-90a4-cf56b85be084' User entered '20 Sep 2020 20:27'	System	21 Sep 2020 00:27:57
	System	21 Sep 2020 00:27:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 3'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:35:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'becce3eb-ff17-4bcc-a7c2-38b8046c4c12'	System	22 Sep 2020 02:35:57
User entered 'Yes (Y)'	System	22 Sep 2020 02:35:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:35:48', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'becce3eb-ff17-4bcc-a7c2-38b8046c4c12' User entered '98.0'	System	22 Sep 2020 02:35:57
	System	22 Sep 2020 02:35:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:35:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'becce3eb-ff17-4bcc-a7c2-38b8046c4c12'	System	22 Sep 2020 02:35:57
User entered 'No (N)'	System	22 Sep 2020 02:35:57

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:35:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'becce3eb-ff17-4bcc-a7c2-38b8046c4c12' User entered '21 Sep 2020 22:35'	System	22 Sep 2020 02:35:57
	System	22 Sep 2020 02:35:57

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 4'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:50:35', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2e7af738-3df4-4945-9bdc-bb9358db58cf' User entered 'Yes (Y)'	System	23 Sep 2020 03:50:51
	System	23 Sep 2020 03:50:51

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:50:42', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2e7af738-3df4-4945-9bdc-bb9358db58cf' User entered '98.0'	System	23 Sep 2020 03:50:51
	System	23 Sep 2020 03:50:51

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:50:46', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2e7af738-3df4-4945-9bdc-bb9358db58cf' User entered 'No (N)'	System	23 Sep 2020 03:50:51
	System	23 Sep 2020 03:50:51

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:50:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2e7af738-3df4-4945-9bdc-bb9358db58cf' User entered '22 Sep 2020 23:50'	System	23 Sep 2020 03:50:51
	System	23 Sep 2020 03:50:51

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 5'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:40:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ad851529-52e3-41de-a311-1c147530f41d' User entered 'Yes (Y)'	System	24 Sep 2020 01:40:55
	System	24 Sep 2020 01:40:55



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:40:47', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ad851529-52e3-41de-a311-1c147530f41d' User entered '98.1'	System	24 Sep 2020 01:40:55
	System	24 Sep 2020 01:40:55

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:40:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ad851529-52e3-41de-a311-1c147530f41d' User entered 'No (N)'	System	24 Sep 2020 01:40:55
	System	24 Sep 2020 01:40:55

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:40:52', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ad851529-52e3-41de-a311-1c147530f41d' User entered '23 Sep 2020 21:40'	System	24 Sep 2020 01:40:55
	System	24 Sep 2020 01:40:55

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 6'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:03:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'fafb9e2b-1d97-4608-8db5-1d577a45f669' User entered 'Yes (Y)'	System	25 Sep 2020 03:04:11
	System	25 Sep 2020 03:04:11

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:03:58', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'fafb9e2b-1d97-4608-8db5-1d577a45f669' User entered '97.9'	System	25 Sep 2020 03:04:11
	System	25 Sep 2020 03:04:11



US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'fafb9e2b-1d97-4608-8db5-1d577a45f669'	System	25 Sep 2020 03:04:11
User entered 'No (N)'	System	25 Sep 2020 03:04:11

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:05', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'fafb9e2b-1d97-4608-8db5-1d577a45f669' User entered '24 Sep 2020 23:04'	System	25 Sep 2020 03:04:11
	System	25 Sep 2020 03:04:11

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:39:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 7'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:23', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7ad76b72-cac9-43db-b661-07c57f273286' User entered 'Yes (Y)'	System	26 Sep 2020 01:41:37
	System	26 Sep 2020 01:41:37

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7ad76b72-cac9-43db-b661-07c57f273286' User entered '98.1'	System	26 Sep 2020 01:41:37
	System	26 Sep 2020 01:41:37

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7ad76b72-cac9-43db-b661-07c57f273286' User entered 'No (N)'	System	26 Sep 2020 01:41:37
	System	26 Sep 2020 01:41:37



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7ad76b72-cac9-43db-b661-07c57f273286' User entered '25 Sep 2020 21:41'	System	26 Sep 2020 01:41:37
	System	26 Sep 2020 01:41:37

US3352200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bbaf1d9f-3296-419f-a8ce-4fd08d8943a4' User entered 'None (1)'	System	19 Sep 2020 19:00:13
	System	19 Sep 2020 19:00:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T14:59:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bbaf1d9f-3296-419f-a8ce-4fd08d8943a4' User entered 'No (N)'	System	19 Sep 2020 19:00:13
	System	19 Sep 2020 19:00:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bbaf1d9f-3296-419f-a8ce-4fd08d8943a4' User entered 'No (N)'	System	19 Sep 2020 19:00:13
	System	19 Sep 2020 19:00:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bbaf1d9f-3296-419f-a8ce-4fd08d8943a4' User entered 'None (1)'	System	19 Sep 2020 19:00:13
	System	19 Sep 2020 19:00:13



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bbaf1d9f-3296-419f-a8ce-4fd08d8943a4' User entered '19 Sep 2020 15:00'	System	19 Sep 2020 19:00:13
	System	19 Sep 2020 19:00:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 14:43'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 17:13'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:18:32', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '27baa2b8-9a1e-42ef-aec6-25e3aede8a07'	System	20 Sep 2020 02:19:43
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 02:19:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:18:40', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '27baa2b8-9a1e-42ef-aec6-25e3aede8a07' User entered 'No (N)'	System	20 Sep 2020 02:19:43
	System	20 Sep 2020 02:19:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '27baa2b8-9a1e-42ef-aec6-25e3aede8a07' User entered 'No (N)'	System	20 Sep 2020 02:19:43
	System	20 Sep 2020 02:19:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '27baa2b8-9a1e-42ef-aec6-25e3aede8a07' User entered 'None (1)'	System	20 Sep 2020 02:19:43
	System	20 Sep 2020 02:19:43



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '27baa2b8-9a1e-42ef-aec6-25e3aede8a07' User entered '19 Sep 2020 22:19'	System	20 Sep 2020 02:19:43
	System	20 Sep 2020 02:19:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 18:08'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 2'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:24:56', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:25:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered 'No (N)'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:25:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered 'Yes (Y)'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:15', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered '20'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:19', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered 'None (1)'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f4b33bb9-9931-4571-b929-a6a45cbb4a1b' User entered '20 Sep 2020 20:26'	System	21 Sep 2020 00:26:29
	System	21 Sep 2020 00:26:29

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 3'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58'	System	22 Sep 2020 02:36:43
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 02:36:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered 'Yes (Y)'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered '15'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:22', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered 'Yes (Y)'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:32', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered '10'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered 'None (1)'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9d00e039-97d3-4f05-b706-b127e22a7b58' User entered '21 Sep 2020 22:36'	System	22 Sep 2020 02:36:43
	System	22 Sep 2020 02:36:43

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 4'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:50:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275'	System	23 Sep 2020 03:51:31
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 03:51:31



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275' User entered 'No (N)'	System	23 Sep 2020 03:51:31
	System	23 Sep 2020 03:51:31

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275' User entered 'Yes (Y)'	System	23 Sep 2020 03:51:31
	System	23 Sep 2020 03:51:31

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275' User entered '5'	System	23 Sep 2020 03:51:31
	System	23 Sep 2020 03:51:31

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:27', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275' User entered 'None (1)'	System	23 Sep 2020 03:51:31
	System	23 Sep 2020 03:51:31

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd7166184-4e1c-4c27-834f-b76099fa9275' User entered '22 Sep 2020 23:51'	System	23 Sep 2020 03:51:31
	System	23 Sep 2020 03:51:31

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 5'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '72de3864-ee3f-4433-acf4-396b8cdfa27f' User entered 'None (1)'	System	24 Sep 2020 01:41:13
	System	24 Sep 2020 01:41:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '72de3864-ee3f-4433-acf4-396b8cdfa27f' User entered 'No (N)'	System	24 Sep 2020 01:41:13
	System	24 Sep 2020 01:41:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:06', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '72de3864-ee3f-4433-acf4-396b8cdfa27f' User entered 'No (N)'	System	24 Sep 2020 01:41:13
	System	24 Sep 2020 01:41:13

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '72de3864-ee3f-4433-acf4-396b8cdfa27f' User entered 'None (1)'	System	24 Sep 2020 01:41:13
	System	24 Sep 2020 01:41:13

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '72de3864-ee3f-4433-acf4-396b8cdfa27f' User entered '23 Sep 2020 21:41'	System	24 Sep 2020 01:41:13
	System	24 Sep 2020 01:41:13

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 6'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8dd7333a-509c-4572-8581-0062b3dee585'	System	25 Sep 2020 03:04:21
User entered 'None (1)'	System	25 Sep 2020 03:04:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8dd7333a-509c-4572-8581-0062b3dee585'	System	25 Sep 2020 03:04:21
User entered 'No (N)'	System	25 Sep 2020 03:04:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8dd7333a-509c-4572-8581-0062b3dee585' User entered 'No (N)'	System	25 Sep 2020 03:04:21
	System	25 Sep 2020 03:04:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:15', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8dd7333a-509c-4572-8581-0062b3dee585'	System	25 Sep 2020 03:04:21
User entered 'None (1)'	System	25 Sep 2020 03:04:21

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:16', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8dd7333a-509c-4572-8581-0062b3dee585' User entered '24 Sep 2020 23:04'	System	25 Sep 2020 03:04:21
	System	25 Sep 2020 03:04:21

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 7'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:10', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c620026-34d6-4086-8ab0-61d8503e60b1' User entered 'None (1)'	System	26 Sep 2020 01:41:21
	System	26 Sep 2020 01:41:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c620026-34d6-4086-8ab0-61d8503e60b1' User entered 'No (N)'	System	26 Sep 2020 01:41:21
	System	26 Sep 2020 01:41:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c620026-34d6-4086-8ab0-61d8503e60b1' User entered 'No (N)'	System	26 Sep 2020 01:41:21
	System	26 Sep 2020 01:41:21

US3352200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:16', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c620026-34d6-4086-8ab0-61d8503e60b1' User entered 'None (1)'	System	26 Sep 2020 01:41:21
	System	26 Sep 2020 01:41:21

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:19', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c620026-34d6-4086-8ab0-61d8503e60b1' User entered '25 Sep 2020 21:41'	System	26 Sep 2020 01:41:21
	System	26 Sep 2020 01:41:21

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Sep 2020 18:41:38



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:16', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'None (0)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:29', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered 'No (N)'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T15:00:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2d586bf9-15d5-462f-bd5e-01be798897fc' User entered '19 Sep 2020 15:00'	System	19 Sep 2020 19:00:38
	System	19 Sep 2020 19:00:38



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 14:43'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 17:13'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 1, after vaccination (at home)'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:47', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:19:59', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'None (0)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered 'No (N)'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-19T22:20:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2c4470b1-1c08-412c-8e3e-89764e4e4f4d' User entered '19 Sep 2020 22:20'	System	20 Sep 2020 02:20:06
	System	20 Sep 2020 02:20:06

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '19 Sep 2020 18:08'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 2'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065'	System	21 Sep 2020 00:27:15
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Sep 2020 00:27:15

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:43', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'None (0)'	System	21 Sep 2020 00:27:15
	System	21 Sep 2020 00:27:15



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:50', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'Significant; prevents daily activity (3)'	System	21 Sep 2020 00:27:15

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'Significant; prevents daily activity (3)'	System	21 Sep 2020 00:27:15

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:26:58', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'None (0)'	System	21 Sep 2020 00:27:15
	System	21 Sep 2020 00:27:15

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'None (0)'	System	21 Sep 2020 00:27:15
	System	21 Sep 2020 00:27:15

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:05', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered 'No (N)'	System	21 Sep 2020 00:27:15
	System	21 Sep 2020 00:27:15

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-20T20:27:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ab09855b-eacb-4877-90dc-ed691f8ca065' User entered '20 Sep 2020 20:27'	System	21 Sep 2020 00:27:15
	System	21 Sep 2020 00:27:15

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 18:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 3'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:46', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff'	System	22 Sep 2020 02:37:22
User entered 'No interference with activity (1)'	System	22 Sep 2020 02:37:22

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:48', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff' User entered 'None (0)'	System	22 Sep 2020 02:37:22
	System	22 Sep 2020 02:37:22

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:52', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff'	System	22 Sep 2020 02:37:22
User entered 'No interference with activity (1)'	System	22 Sep 2020 02:37:22

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:36:56', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff' User entered 'None (0)'	System	22 Sep 2020 02:37:22
	System	22 Sep 2020 02:37:22

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:37:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff'	System	22 Sep 2020 02:37:22
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 02:37:22

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:37:03', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff' User entered 'None (0)'	System	22 Sep 2020 02:37:22
	System	22 Sep 2020 02:37:22

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:37:06', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff' User entered 'No (N)'	System	22 Sep 2020 02:37:22
	System	22 Sep 2020 02:37:22



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-21T22:37:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7cf4f5af-5d47-47ab-92d6-ae1a5eebf0ff' User entered '21 Sep 2020 22:37'	System	22 Sep 2020 02:37:22
	System	22 Sep 2020 02:37:22

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 4'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'None (0)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:40', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'None (0)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:42', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'None (0)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:44', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'None (0)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:49', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557'	System	23 Sep 2020 03:51:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 03:51:59

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'None (0)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered 'No (N)'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-22T23:51:55', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '058d25dc-1d9f-4e7e-a753-7212c0abc557' User entered '22 Sep 2020 23:51'	System	23 Sep 2020 03:51:59
	System	23 Sep 2020 03:51:59

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '22 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 5'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:16', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'None (0)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:18', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'None (0)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:21', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'None (0)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:24', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'None (0)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127'	System	24 Sep 2020 01:41:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 01:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'None (0)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:32', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered 'No (N)'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-23T21:41:35', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'be428b00-8349-448b-b5c7-47fc8a5a2127' User entered '23 Sep 2020 21:41'	System	24 Sep 2020 01:41:38
	System	24 Sep 2020 01:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '23 Sep 2020 12:00'	System	19 Sep 2020 18:41:38



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 6'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:23', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'No interference with activity (1)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'None (0)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:27', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'None (0)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:29', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'None (0)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:32', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d'	System	25 Sep 2020 03:04:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'None (0)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:37', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered 'No (N)'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-24T23:04:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '2959a1ac-fb97-46b5-b986-5e090a189e3d' User entered '24 Sep 2020 23:04'	System	25 Sep 2020 03:04:42
	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '24 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	19 Sep 2020 18:41:38
User entered 'Day 7'	System	19 Sep 2020 18:41:38

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'None (0)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:35', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'None (0)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:36', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'None (0)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08



US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'None (0)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5'	System	26 Sep 2020 01:41:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:51', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'None (0)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

US3352200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:40:58', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered 'No (N)'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-25T21:41:06', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1fa84f32-e35f-49b8-bb89-1de6f78ecce5' User entered '25 Sep 2020 21:41'	System	26 Sep 2020 01:41:08
	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '25 Sep 2020 12:00'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Sep 2020 11:59'	System	19 Sep 2020 18:41:38

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	25 Sep 2020 03:04:42
User entered 'Day 8'	System	25 Sep 2020 03:04:42



US3352200

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(8)

Generated On: 11 Aug 2021 22:39:36

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: Nausea\_Day(9)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	26 Sep 2020 01:41:08
User entered 'Day 9'	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-27T23:11:58', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '83f8c830-a3cf-4387-b120-7ab83be012bf' User entered 'None (0)'	System	28 Sep 2020 03:12:04
	System	28 Sep 2020 03:12:04

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-27T23:12:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '83f8c830-a3cf-4387-b120-7ab83be012bf' User entered '27 Sep 2020 23:12'	System	28 Sep 2020 03:12:04
	System	28 Sep 2020 03:12:04

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 01:41:08



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Nausea\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	25 Sep 2020 03:04:42
User entered 'Day 8'	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 03:04:42

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 03:04:42

US3352200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:39:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	26 Sep 2020 01:41:08
User entered 'Day 9'	System	26 Sep 2020 01:41:08

US3352200

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-27T23:12:06', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd61a32c7-0225-4d0c-b240-1cec1a637197' User entered 'No (N)'	System	28 Sep 2020 03:12:10
	System	28 Sep 2020 03:12:10



**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-09-27T23:12:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd61a32c7-0225-4d0c-b240-1cec1a637197' User entered '27 Sep 2020 23:12'	System	28 Sep 2020 03:12:10
	System	28 Sep 2020 03:12:10

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:39:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 01:41:08

**US3352200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Sep 2020 19:27:41

**US3352200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '27 Sep 2020'	(b) (4), (b) (6)	27 Sep 2020 19:27:41

US3352200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Sep 2020 19:27:41

US3352200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:27:41

US3352200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Sep 2020 19:30:45



**US3352200**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:55:37
User entered 'I'	System	27 Sep 2020 19:30:45

**US3352200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 15:21:17

US3352200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '3 Oct 2020'	(b) (4), (b) (6)	03 Oct 2020 15:21:17

US3352200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Oct 2020 15:21:17

**US3352200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	03 Oct 2020 15:21:17

US3352200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Oct 2020 15:21:21

**US3352200**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:10:11
User entered 'I'	System	03 Oct 2020 15:21:21

**US3352200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 14:47:50



US3352200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '10 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 14:47:50

US3352200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Oct 2020 14:47:50

**US3352200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 14:47:50

US3352200

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 14:47:54

**US3352200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:43
User entered 'I'	System	10 Oct 2020 14:47:54

US3352200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:28:21

US3352200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:28:21

US3352200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 17:28:21



**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'VISIT3'	System	15 Oct 2020 17:28:21

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '11:13'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered '15 Oct 2020 11:13'	System	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '36.7' C	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:28:49



US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '67'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'bpm'	System	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '14'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'breaths/min'	System	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '102'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'mmHg'	System	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '69'	(b) (4), (b) (6)	15 Oct 2020 17:28:49

US3352200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'mmHg'	System	15 Oct 2020 17:28:49



**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:13:18

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 08:13:18

US3352200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 17:28:57

US3352200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:28:57

US3352200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:29:23

US3352200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:29:23

US3352200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '11:39'	(b) (4), (b) (6)	15 Oct 2020 17:29:23

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered '15 Oct 2020 11:39'	System	15 Oct 2020 17:29:23



US3352200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:29:28

**US3352200**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:18
User entered 'I'	System	15 Oct 2020 17:29:28

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 64'	System	22 Aug 2020 17:52:18

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-10-23T15:15:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '6cd88d2d-cad0-44a9-af9b-4b89ff02b037'	System	23 Oct 2020 19:15:41
User entered 'No (N)'	System	23 Oct 2020 19:15:41

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

Have you been exposed to someone with 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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-10-23T15:15:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '6cd88d2d-cad0-44a9-af9b-4b89ff02b037'	System	23 Oct 2020 19:15:41
User entered 'No (N)'	System	23 Oct 2020 19:15:41

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-10-23T15:15:35', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '6cd88d2d-cad0-44a9-af9b-4b89ff02b037' User entered '23 Oct 2020 15:15:35'	System	23 Oct 2020 19:15:41
	System	23 Oct 2020 19:15:41

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 17:52:18



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 71'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 78'	System	22 Aug 2020 17:52:18

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

[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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-08T20:54:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bf4fac7c-1ab6-4df7-a824-fc1ca8414b3b' User entered 'No (N)'	System	09 Nov 2020 01:55:11
	System	09 Nov 2020 01:55:11

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-08T20:55:02', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bf4fac7c-1ab6-4df7-a824-fc1ca8414b3b'	System	09 Nov 2020 01:55:11
User entered 'No (N)'	System	09 Nov 2020 01:55:11

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-08T20:55:06', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'bf4fac7c-1ab6-4df7-a824-fc1ca8414b3b' User entered '08 Nov 2020 20:55:06'	System	09 Nov 2020 01:55:11
	System	09 Nov 2020 01:55:11



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:32:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered 'Day 92'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

US3352200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:36

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:15:52
Data entry locked.	System	22 Aug 2020 17:52:18
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 17:52:18

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-20T18:27:46', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '63a74ad0-e132-4ff3-b3cd-91b442cc6f14'	System	20 Nov 2020 23:27:57
User entered 'No (N)'	System	20 Nov 2020 23:27:57



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-20T18:27:50', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '63a74ad0-e132-4ff3-b3cd-91b442cc6f14'	System	20 Nov 2020 23:27:57
User entered 'No (N)'	System	20 Nov 2020 23:27:57

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-20T18:27:54', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '63a74ad0-e132-4ff3-b3cd-91b442cc6f14' User entered '20 Nov 2020 18:27:54'	System	20 Nov 2020 23:27:57
	System	20 Nov 2020 23:27:57

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-24T14:21:56', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c75e30-3e62-4745-80e4-2310e186bdd7'	System	24 Nov 2020 19:22:03
User entered 'No (N)'	System	24 Nov 2020 19:22:03

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-24T14:21:57', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c75e30-3e62-4745-80e4-2310e186bdd7'	System	24 Nov 2020 19:22:03
User entered 'No (N)'	System	24 Nov 2020 19:22:03

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-11-24T14:22:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '04c75e30-3e62-4745-80e4-2310e186bdd7' User entered '24 Nov 2020 14:22:00'	System	24 Nov 2020 19:22:03
	System	24 Nov 2020 19:22:03



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-03T18:44:25', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b0d1e0a6-7266-453a-9e72-6eedd620a1a4'	System	03 Dec 2020 23:44:36
User entered 'No (N)'	System	03 Dec 2020 23:44:36

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-03T18:44:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b0d1e0a6-7266-453a-9e72-6eedd620a1a4'	System	03 Dec 2020 23:44:36
User entered 'No (N)'	System	03 Dec 2020 23:44:36

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-03T18:44:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b0d1e0a6-7266-453a-9e72-6eedd620a1a4' User entered '03 Dec 2020 18:44:31'	System	03 Dec 2020 23:44:36
	System	03 Dec 2020 23:44:36

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-08T17:44:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'da5033cc-3219-423e-ac67-0b4289f085b2' User entered 'No (N)'	System	08 Dec 2020 22:44:43
	System	08 Dec 2020 22:44:43

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-08T17:44:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'da5033cc-3219-423e-ac67-0b4289f085b2'	System	08 Dec 2020 22:44:43
User entered 'No (N)'	System	08 Dec 2020 22:44:43

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-08T17:44:42', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'da5033cc-3219-423e-ac67-0b4289f085b2' User entered '08 Dec 2020 17:44:42'	System	08 Dec 2020 22:44:43
	System	08 Dec 2020 22:44:43

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-14T15:09:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1a4ce939-daa3-4ae9-9f77-853cbf19a92f' User entered 'No (N)'	System	14 Dec 2020 20:09:09
	System	14 Dec 2020 20:09:09



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-14T15:09:03', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1a4ce939-daa3-4ae9-9f77-853cbf19a92f' User entered 'No (N)'	System	14 Dec 2020 20:09:09
	System	14 Dec 2020 20:09:09

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-14T15:09:05', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1a4ce939-daa3-4ae9-9f77-853cbf19a92f' User entered '14 Dec 2020 15:09:05'	System	14 Dec 2020 20:09:09
	System	14 Dec 2020 20:09:09

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-21T16:56:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '55f08c5e-bec3-4362-bf0f-ec3c1e57d5cd' User entered 'No (N)'	System	21 Dec 2020 21:56:23
	System	21 Dec 2020 21:56:23

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-21T16:56:13', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '55f08c5e-bec3-4362-bf0f-ec3c1e57d5cd' User entered 'No (N)'	System	21 Dec 2020 21:56:23
	System	21 Dec 2020 21:56:23

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-21T16:56:19', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '55f08c5e-bec3-4362-bf0f-ec3c1e57d5cd' User entered '21 Dec 2020 16:56:19'	System	21 Dec 2020 21:56:23
	System	21 Dec 2020 21:56:23



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-29T08:35:04', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b44b2c27-483f-4906-bb6f-16a0106f0639' User entered 'No (N)'	System	29 Dec 2020 13:35:17
	System	29 Dec 2020 13:35:17

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-29T08:35:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b44b2c27-483f-4906-bb6f-16a0106f0639'	System	29 Dec 2020 13:35:17
User entered 'No (N)'	System	29 Dec 2020 13:35:17

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2020-12-29T08:35:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b44b2c27-483f-4906-bb6f-16a0106f0639' User entered '29 Dec 2020 08:35:12'	System	29 Dec 2020 13:35:17
	System	29 Dec 2020 13:35:17

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-04T08:40:01', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '74b7078f-dfac-4e26-ae4b-ef2d59acde59' User entered 'No (N)'	System	04 Jan 2021 13:40:13
	System	04 Jan 2021 13:40:13

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-04T08:40:08', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '74b7078f-dfac-4e26-ae4b-ef2d59acde59' User entered 'No (N)'	System	04 Jan 2021 13:40:13

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-04T08:40:11', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '74b7078f-dfac-4e26-ae4b-ef2d59acde59' User entered '04 Jan 2021 08:40:11'	System	04 Jan 2021 13:40:13
	System	04 Jan 2021 13:40:13

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-13T12:58:34', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd97316ed-6369-4199-879b-4dbc5e07c0be' User entered 'No (N)'	System	13 Jan 2021 17:58:46
	System	13 Jan 2021 17:58:46



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-13T12:58:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd97316ed-6369-4199-879b-4dbc5e07c0be' User entered 'No (N)'	System	13 Jan 2021 17:58:46

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-13T12:58:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'd97316ed-6369-4199-879b-4dbc5e07c0be' User entered '13 Jan 2021 12:58:41'	System	13 Jan 2021 17:58:46
	System	13 Jan 2021 17:58:46

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-20T14:01:09', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9ec4eee2-87ef-45af-a50d-6f3426d8ed8b' User entered 'No (N)'	System	20 Jan 2021 19:01:24
	System	20 Jan 2021 19:01:24

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-20T14:01:19', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9ec4eee2-87ef-45af-a50d-6f3426d8ed8b' User entered 'No (N)'	System	20 Jan 2021 19:01:24

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-20T14:01:22', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '9ec4eee2-87ef-45af-a50d-6f3426d8ed8b' User entered '20 Jan 2021 14:01:22'	System	20 Jan 2021 19:01:24
	System	20 Jan 2021 19:01:24



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-27T09:59:39', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '4840b543-111b-48cc-82f2-31710613784e' User entered 'No (N)'	System	27 Jan 2021 14:59:57
	System	27 Jan 2021 14:59:57

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-27T09:59:47', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '4840b543-111b-48cc-82f2-31710613784e' User entered 'No (N)'	System	27 Jan 2021 14:59:57
	System	27 Jan 2021 14:59:57

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-01-27T09:59:53', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '4840b543-111b-48cc-82f2-31710613784e' User entered '27 Jan 2021 09:59:53'	System	27 Jan 2021 14:59:57
	System	27 Jan 2021 14:59:57

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-02T17:19:12', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f75bb6d1-4c01-4ea2-89a9-a2ce91139a28'	System	02 Feb 2021 22:19:22
User entered 'No (N)'	System	02 Feb 2021 22:19:22

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-02T17:19:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f75bb6d1-4c01-4ea2-89a9-a2ce91139a28'	System	02 Feb 2021 22:19:22
User entered 'No (N)'	System	02 Feb 2021 22:19:22

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-02T17:19:17', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'f75bb6d1-4c01-4ea2-89a9-a2ce91139a28' User entered '02 Feb 2021 17:19:17'	System	02 Feb 2021 22:19:22
	System	02 Feb 2021 22:19:22

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-11T21:15:33', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '97215961-5fca-406d-b2a6-e430ee8130dc' User entered 'No (N)'	System	12 Feb 2021 02:23:27



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-11T21:15:38', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '97215961-5fca-406d-b2a6-e430ee8130dc' User entered 'No (N)'	System	12 Feb 2021 02:23:27

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-11T21:15:41', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '97215961-5fca-406d-b2a6-e430ee8130dc' User entered '11 Feb 2021 21:15:41'	System	12 Feb 2021 02:23:27

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-17T13:31:13', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e7fcce4-a8a9-43a5-b8be-cc113286e5ba' User entered 'No (N)'	System	17 Feb 2021 18:31:20
	System	17 Feb 2021 18:31:20

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-17T13:31:14', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e7fcce4-a8a9-43a5-b8be-cc113286e5ba' User entered 'No (N)'	System	17 Feb 2021 18:31:20
	System	17 Feb 2021 18:31:20

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-17T13:31:17', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '7e7fcce4-a8a9-43a5-b8be-cc113286e5ba' User entered '17 Feb 2021 13:31:17'	System	17 Feb 2021 18:31:20
	System	17 Feb 2021 18:31:20



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-24T10:13:26', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ddf1c35c-3a30-4649-9928-620215290b81' User entered 'No (N)'	System	24 Feb 2021 15:13:37
	System	24 Feb 2021 15:13:37

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-24T10:13:28', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ddf1c35c-3a30-4649-9928-620215290b81' User entered 'No (N)'	System	24 Feb 2021 15:13:37
	System	24 Feb 2021 15:13:37

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-24T10:13:31', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ddf1c35c-3a30-4649-9928-620215290b81' User entered '24 Feb 2021 10:13:31'	System	24 Feb 2021 15:13:37
	System	24 Feb 2021 15:13:37

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-03T12:00:56-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '60963c42-38c2-4bfa-8798-3525475099d1'	System	03 Mar 2021 17:03:28
User entered 'No (N)'	System	03 Mar 2021 17:03:28

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-03T12:00:58-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '60963c42-38c2-4bfa-8798-3525475099d1'	System	03 Mar 2021 17:03:28
User entered 'No (N)'	System	03 Mar 2021 17:03:28

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-03T12:01:01-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '60963c42-38c2-4bfa-8798-3525475099d1'	System	03 Mar 2021 17:03:28
User entered '03 Mar 2021 17:01:01'	System	03 Mar 2021 17:03:28

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-08T06:36:53-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '29a36043-def5-42e7-b636-d8b2ef78db38'	System	08 Mar 2021 11:37:08
User entered 'No (N)'	System	08 Mar 2021 11:37:08



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-08T06:36:55-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '29a36043-def5-42e7-b636-d8b2ef78db38'	System	08 Mar 2021 11:37:08
User entered 'No (N)'	System	08 Mar 2021 11:37:08

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-08T06:37:04-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '29a36043-def5-42e7-b636-d8b2ef78db38' User entered '08 Mar 2021 06:37:04'	System	08 Mar 2021 11:37:08
	System	08 Mar 2021 11:37:08

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-16T18:12:49-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'df1e3232-bc87-49a8-8707-f00ddd9a5f30'	System	16 Mar 2021 22:16:01
User entered 'No (N)'	System	16 Mar 2021 22:16:01

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-16T18:12:51-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'df1e3232-bc87-49a8-8707-f00ddd9a5f30'	System	16 Mar 2021 22:16:01
User entered 'No (N)'	System	16 Mar 2021 22:16:01

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-16T18:12:53-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'df1e3232-bc87-49a8-8707-f00ddd9a5f30'	System	16 Mar 2021 22:16:01
User entered '16 Mar 2021 18:12:53'	System	16 Mar 2021 22:16:01



**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-24T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b68ef49d-46ca-47cf-ae77-36fe17c353c9'	System	24 Mar 2021 16:01:11
User entered 'No (N)'	System	24 Mar 2021 16:01:11

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-24T12:00:25-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b68ef49d-46ca-47cf-ae77-36fe17c353c9'	System	24 Mar 2021 16:01:11
User entered 'No (N)'	System	24 Mar 2021 16:01:11

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-24T12:00:30-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b68ef49d-46ca-47cf-ae77-36fe17c353c9'	System	24 Mar 2021 16:01:11
User entered '24 Mar 2021 12:00:30'	System	24 Mar 2021 16:01:11

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-30T16:50:58-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '84624730-8f58-400f-8340-ad5b00f38527'	System	30 Mar 2021 20:51:12
User entered 'No (N)'	System	30 Mar 2021 20:51:12

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-30T16:51:00-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '84624730-8f58-400f-8340-ad5b00f38527'	System	30 Mar 2021 20:51:12
User entered 'No (N)'	System	30 Mar 2021 20:51:12

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-03-30T16:51:08-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '84624730-8f58-400f-8340-ad5b00f38527' User entered '30 Mar 2021 16:51:08'	System	30 Mar 2021 20:51:12
	System	30 Mar 2021 20:51:12

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-06T17:09:46-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1222f387-8a14-48bc-9e3f-f61b1eccf13d' User entered 'No (N)'	System	06 Apr 2021 21:09:54



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-06T17:09:47-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1222f387-8a14-48bc-9e3f-f61b1eccf13d' User entered 'No (N)'	System	06 Apr 2021 21:09:54

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-06T17:09:50-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '1222f387-8a14-48bc-9e3f-f61b1eccf13d'	System	06 Apr 2021 21:09:54
User entered '06 Apr 2021 17:09:50'	System	06 Apr 2021 21:09:54

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-12T15:48:12-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8e4d4d18-21ff-4268-ab1d-8e41eb9b9d00'	System	12 Apr 2021 19:48:43
User entered 'No (N)'	System	12 Apr 2021 19:48:43

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-12T15:48:15-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8e4d4d18-21ff-4268-ab1d-8e41eb9b9d00' User entered 'No (N)'	System	12 Apr 2021 19:48:43
	System	12 Apr 2021 19:48:43

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-12T15:48:25-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '8e4d4d18-21ff-4268-ab1d-8e41eb9b9d00'	System	12 Apr 2021 19:48:43
User entered '12 Apr 2021 15:48:25'	System	12 Apr 2021 19:48:43



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-20T18:02:02-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'edd1e96c-982d-4413-a4b5-a32be41786cd' User entered 'No (N)'	System	20 Apr 2021 22:05:58
	System	20 Apr 2021 22:05:58

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-20T18:02:04-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'edd1e96c-982d-4413-a4b5-a32be41786cd' User entered 'No (N)'	System	20 Apr 2021 22:05:58

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-20T18:02:07-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'edd1e96c-982d-4413-a4b5-a32be41786cd' User entered '20 Apr 2021 18:02:07'	System	20 Apr 2021 22:05:58
	System	20 Apr 2021 22:05:58

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-29T17:59:16-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b4eea0c9-fd87-4c7c-91e6-0fb20826c3a0'	System	29 Apr 2021 21:59:27
User entered 'No (N)'	System	29 Apr 2021 21:59:27

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-29T17:59:18-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b4eea0c9-fd87-4c7c-91e6-0fb20826c3a0'	System	29 Apr 2021 21:59:27
User entered 'No (N)'	System	29 Apr 2021 21:59:27

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-04-29T17:59:21-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'b4eea0c9-fd87-4c7c-91e6-0fb20826c3a0' User entered '29 Apr 2021 17:59:21'	System	29 Apr 2021 21:59:27
	System	29 Apr 2021 21:59:27

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-05-03T08:32:35-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ea56c5ab-0e8f-47ba-90e7-929c3b9831ca' User entered 'No (N)'	System	03 May 2021 12:32:43



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Have you been exposed to someone with 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 (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-05-03T08:32:37-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ea56c5ab-0e8f-47ba-90e7-929c3b9831ca' User entered 'No (N)'	System	03 May 2021 12:32:43

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-05-03T08:32:40-04:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: 'ea56c5ab-0e8f-47ba-90e7-929c3b9831ca'	System	03 May 2021 12:32:43
User entered '03 May 2021 08:32:40'	System	03 May 2021 12:32:43

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:15:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:15:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:15:52



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:15:52



**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:15:52

**US3352200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:39:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:15:52
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:15:52

US3352200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:39:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-28T13:41:27-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '205a3ec8-acd1-48a5-b7c4-7cee7d793904'	System	28 Feb 2021 18:41:37
User entered 'No (N)'	System	28 Feb 2021 18:41:37

**US3352200**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC89BBB0-12FB-4821-A371-22D5A4F67E53)', Time: '2021-02-28T13:41:34-05:00', User OID: 'PatientReportedOutcome (US3352200)', ODM File OID: '205a3ec8-acd1-48a5-b7c4-7cee7d793904' User entered '28 Feb 2021 18:41:34'	System	28 Feb 2021 18:41:37
	System	28 Feb 2021 18:41:37

US3352200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 17:28:22

US3352200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 17:28:22

US3352200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 17:28:22



US3352200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 17:28:22

US3352200

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 17:28:26

**US3352200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:22:13
User entered 'I'	System	13 Nov 2020 17:28:26

US3352200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:04:21

**US3352200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 20:04:21

US3352200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 20:04:21

**US3352200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 20:04:21

US3352200

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:04:29



**US3352200**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User entered 'I'	System	17 Dec 2020 20:04:29

**US3352200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Jan 2021 14:54:17

US3352200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '15 Jan 2021'	Yulexis Amestoy (b) (4)	15 Jan 2021 14:54:17

**US3352200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	15 Jan 2021 14:54:17

US3352200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Yulexis Amestoy (b) (4)	15 Jan 2021 14:54:17

US3352200

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Jan 2021 14:54:10

**US3352200**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User entered 'I'	System	15 Jan 2021 14:54:10

**US3352200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:30:21



**US3352200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 18:30:21

**US3352200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 18:30:21

**US3352200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 18:30:21

US3352200

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 18:30:31

**US3352200**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:35:03
User entered 'I'	System	17 Feb 2021 18:30:31

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 14:55:02

US3352200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 14:55:02

US3352200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Mar 2021 14:55:02



**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered 'VISIT4'	System	18 Mar 2021 14:55:02

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09



US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 23:57:09

US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	30 Mar 2021 23:57:09



US3352200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:36

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:39:36**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46

US3352200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'No (N)'	(b) (4), (b) (6)	18 Mar 2021 14:55:18

US3352200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 14:55:18

US3352200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 14:55:29

US3352200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 14:55:29

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered '09:02'	(b) (4), (b) (6)	18 Mar 2021 14:55:29

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered '18 Mar 2021 09:02'	System	18 Mar 2021 14:55:29



US3352200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 14:55:33

**US3352200**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered 'I'	System	18 Mar 2021 14:55:33

**US3352200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:39:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	14 Apr 2021 18:21:45

US3352200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '14 Apr 2021'	Yulexis Amestoy (b) (4)	14 Apr 2021 18:21:45

US3352200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	14 Apr 2021 18:21:45

US3352200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:36

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Yulexis Amestoy (b) (4)	14 Apr 2021 18:21:45

US3352200

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	14 Apr 2021 18:21:49

**US3352200**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 18:21:49



US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:26

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:26

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:36

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:26

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:39:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 17:52:26

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:39:36**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Yulexis Amestoy (b) (4)	26 Mar 2021 14:20:39
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 17:20:44

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Amendment 6 or later (Amendment 6 or later)'	Yulexis Amestoy (b) (4)	26 Mar 2021 14:20:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:20:44



US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:39:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:39

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:39:36**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	26 Jan 2021 17:52:39

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:39:36**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered empty.	System	26 Jan 2021 17:52:39

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:52



US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:52

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '10:14'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:52

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered '26 Jan 2021 10:14'	System	26 Jan 2021 17:52:52

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:39:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:59

US3352200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:59

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '10:09'	Matthew Muniz (b) (4)	26 Jan 2021 17:52:59

**US3352200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:39:36**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:45:46
User entered '26 Jan 2021 10:09'	System	26 Jan 2021 17:52:59

**US3352200**

**Folder: Unscheduled 26 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 20:54:54



US3352200

Folder: Unscheduled 26 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:36

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Matthew Muniz (b) (4)	26 Jan 2021 20:54:54

**US3352200**

**Folder: Unscheduled 26 Jan 2021**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:39:36**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Matthew Muniz (b) (4)	26 Jan 2021 20:54:54

US3352200

Folder: **Unscheduled 26 Jan 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:39:36**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Matthew Muniz (b) (4)	26 Jan 2021 20:54:54

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:36

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:11
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'I'	Matthew Muniz (b) (4)	26 Jan 2021 20:54:54

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '26 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Urine (URINE)'	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'PV Query Urgent: Please confirm positive. If so, please provide the Pregnancy Report form for this reported positive pregnancy for the subject to Safety_Moderna@iqvia.com or fax to 866.599.1342. If not, please update to NO.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 19:13:29
Query 'PV Query Urgent: Please confirm positive. If so, please provide the Pregnancy Report form for this reported positive pregnancy for the subject to Safety_Moderna@iqvia.com or fax to 866.599.1342. If not, please update to NO.' answered with 'Form will be submitted.' (Site from Safety).	Surisaday Mederos (b) (4)	17 Feb 2021 18:01:37
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 04:32:30
User opened query 'PV Query Urgent: Please confirm positive. If so, please provide the Pregnancy Report form for this reported positive pregnancy for the subject to Safety_Moderna@iqvia.com or fax to 866.599.1342. If not, please update to NO.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 15:06:35
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'form submitted' (Site from System).	Matthew Muniz (b) (4)	26 Jan 2021 20:57:43
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	26 Jan 2021 20:56:28
User entered 'Positive (POSITIVE)'	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28



US3352200

Folder: Unscheduled 26 Jan 2021

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:36

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

**US3352200**

**Folder: Unscheduled 26 Jan 2021**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

**US3352200**

**Folder: Unscheduled 26 Jan 2021**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Matthew Muniz (b) (4)	26 Jan 2021 20:56:28

**US3352200**

**Folder: Unscheduled 26 Jan 2021**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:39:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:42:16
User entered empty.	System	26 Jan 2021 20:56:28

US3352200

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:39:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Matthew Muniz (b) (4)	08 Dec 2020 15:40:37

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:39:36**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:14:21
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:29:42

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:31:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 18:31:14
Data point term sent to Coder	System	22 Aug 2020 18:30:57
User entered 'TYLENOL'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'MIGRAINES'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '1000'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:30:34



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'UN UNK 2015'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:30:34

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:30:34

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:30:34

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:30:34

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 18:30:34



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:30:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:30:44
Data point term sent to Coder	System	03 Sep 2020 17:29:55
User entered 'tylenol'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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)	10 Dec 2020 07:36:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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 'please refer to e diary, did not meet the AE reporting criteria' (Site from DM).	Matthew Muniz (b) (4)	09 Dec 2020 15:25:59

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[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 timeframe. 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 of 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). User entered 'headache'	(b) (4), (b) (6) [REDACTED]  Wanda Delgado (b) (4) [REDACTED] [REDACTED]	02 Dec 2020 13:52:35           03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '975'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mg (mg)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'once (ONCE)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (ORAL)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '23 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '23 Aug 2020'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM CLR re-query: thank you for your answer. However, please consider changing this field from no to yes or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:05:02
Query 'Per CDM CLR re-query: thank you for your answer. However, please consider changing this field from no to yes or clarify otherwise. Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	26 Jan 2021 21:04:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	26 Jan 2021 21:04:14
User opened query 'Per CDM CLR re-query: thank you for your answer. However, please consider changing this field from no to yes or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:45:15
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this field should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 12:45:15
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this field should be updated. Else, provide clarification on query response.' answered with 'correct as entered ' (Site from DM).	Matthew Muniz (b) (4)	18 Jan 2021 15:15:37
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this field should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 04:26:35



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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)	18 Nov 2020 07:48:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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.	(b) (4), (b) (6)	17 Nov 2020 19:54:51
' answered with 'Symptom not considered an AE.' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:54:31
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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.	(b) (4), (b) (6)	30 Oct 2020 03:31:10
' (Site from DM).		

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EAB) (1725)

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US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	03 Sep 2020 17:29:22

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User entered empty.	System	03 Sep 2020 17:29:22

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User entered empty.	System	03 Sep 2020 17:29:22

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:18
User entered empty.	System	03 Sep 2020 17:29:22

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 19:42:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 19:42:44
Data point term sent to Coder	System	27 Sep 2020 19:42:01
User entered 'TYLENOL'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'HEADACHE'	(b) (4), (b) (6)	27 Sep 2020 19:41:33



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '1000'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '20 Sep 2020'	(b) (4), (b) (6)	27 Sep 2020 19:41:33



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '20 Sep 2020'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:51:04
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'please refer to diary day 2' (Site from DM).	Matthew Muniz (b) (4)	20 Nov 2020 18:46:34
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 03:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Sep 2020 19:41:33

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User entered empty.	System	27 Sep 2020 19:41:33

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User entered empty.	System	27 Sep 2020 19:41:33

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:20
User entered empty.	System	27 Sep 2020 19:41:33

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 19:43:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 19:43:44
Data point term sent to Coder	System	27 Sep 2020 19:43:01
User entered 'TYLENOL'	(b) (4), (b) (6)	27 Sep 2020 19:42:17



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'FEVER'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '1000'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
Reviewed for Data Management.	(b) (4), (b) (6)	30 Oct 2020 03:32:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Sep 2020 19:42:17



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '20 Sep 2020'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '20 Sep 2020'	(b) (4), (b) (6)	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM CLR re-query: Please be aware that corresponding AE is still not entered. Please enter missing AE for that. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:34:25
Query 'Per CDM CLR re-query: Please be aware that corresponding AE is still not entered. Please enter missing AE for that. Thank you!' answered with 'medication taken for fever on eduary date' (Site from DM).	Matthew Muniz (b) (4)	20 Nov 2020 19:13:13
User opened query 'Per CDM CLR re-query: Please be aware that corresponding AE is still not entered. Please enter missing AE for that. Thank you!' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:20:57
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:20:34
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'Data confirmed, fever/pain reported in eduary ' (Site from DM).	Wanda Delgado (b) (4)	14 Nov 2020 14:05:51

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 03:32:21
	(b) (4), (b) (6) (b) (4), (b) (6)	27 Sep 2020 19:42:17

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User entered empty.	System	27 Sep 2020 19:42:17



**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User entered empty.	System	27 Sep 2020 19:42:17

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:23
User entered empty.	System	27 Sep 2020 19:42:17

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 06:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 06:41:28
Data point term sent to Coder	System	19 Mar 2021 17:10:04
Coding entries removed.	Matthew Muniz (b) (4)	19 Mar 2021 17:09:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:19:42
Data point term sent to Coder	System	12 Mar 2021 16:25:37
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 16:24:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:30:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:30:27
Data point term sent to Coder	System	26 Jan 2021 21:06:44
User entered 'one a day'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: If subject uses vitamins then please consider updating prophylaxis from NO to YES. Also, please review indication. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:45:02
Query 'Per CDM: If subject uses vitamins then please consider updating prophylaxis from NO to YES. Also, please review indication. Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	19 Mar 2021 17:10:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Mar 2021 17:09:50
User opened query 'Per CDM: If subject uses vitamins then please consider updating prophylaxis from NO to YES. Also, please review indication. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:27:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 16:24:40
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User closed query 'Per CDM: Please clarify if subject is pregnant because "Multivitamins pregnancy" is used when subject is pregnant. If subject uses birth control then please consider updating indication accordingly. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:45:19
Query 'Per CDM: Please clarify if subject is pregnant because "Multivitamins pregnancy" is used when subject is pregnant. If subject uses birth control then please consider updating indication accordingly. Thank you!' answered with 'indication updated' (Site from DM).	Matthew Muniz (b) (4)	19 Mar 2021 17:10:05
User entered 'MULTIVITAMIN' reason for change: Data Entry Error	Matthew Muniz (b) (4)	19 Mar 2021 17:09:50
User opened query 'Per CDM: Please clarify if subject is pregnant because "Multivitamins pregnancy" is used when subject is pregnant. If subject uses birth control then please consider updating indication accordingly. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:26:37
User closed query 'Per CDM: Please clarify the use of medication. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 07:33:29
Query 'Per CDM: Please clarify the use of medication. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:24:57
User entered 'MULTIVITAMINS PREGNANCY' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 16:24:40
User opened query 'Per CDM: Please clarify the use of medication. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:35:48
User entered 'pregnancy'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '1'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Other (OTHER)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'cap'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'once daily (QD)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '20 Jan 2021'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered '0'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered empty.	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58



US3352200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Jan 2021 21:05:58

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 21:05:58

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 21:05:58

**US3352200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:39:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 21:05:58

US3352200

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:39:36**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 13:10:04
User entered 'No (N)'	Yulexis Amestoy (b) (4)	26 Mar 2021 14:19:57