

US3372110 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:38:46

All time stamps listed in this document are displayed in GMT

US3372110

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

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[Participant ID](#)

US3372110

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

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US3372110

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3372110

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3372110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3372110

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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Were any significant conditions reported?

Yes ☒

No ☐

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US3372110

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3372110

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	24 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372110

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3372110

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3372110

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	SINUS OSTIAL DILATION
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3372110

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	REMOVAL OF SINUS POLYPS
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

US3372110

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	CLEFT LIP
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3372110

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	CLEFT LIP REPAIR
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3372110

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Condition	SINUS POLYPS
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



US3372110

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:06 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:06
Height ( <i>xxx.x</i> )	183.4 cm
Weight ( <i>xxx.x</i> )	117.8 kg
BMI ( <i>xxx.x</i> )	35.02246 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372110

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3372110

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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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 ☐

**Specify**

LAWYER WORKS IN OFFICE  
ENVIRONMENT WITH APPROX  
100 OTHER EMPLOYEES

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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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

18 of 1806

US3372110

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

<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>	

US3372110

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103567

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 ☒

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Height	ND - Not Done
Weight	ND - Not Done

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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)	13 AUG 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 10:06
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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)	13 AUG 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 12:59
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 11:28 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 11:28

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

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

10:51 (24 HR)

Collection date and time (derived)

13 AUG 2020 10:51

US3372110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:51	13 AUG 2020 10:51
Nasopharyngeal Swab 2	No		

US3372110

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:17

PC Open Date & Time

13 AUG 2020 11:48

PC Close Date & Time

13 AUG 2020 14:18

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	13 AUG 2020 15:14
PC Open Date & Time	13 AUG 2020 15:13
PC Close Date & Time	14 AUG 2020 11:59



US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

14 AUG 2020 12:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**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

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:46

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:46

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.3 °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

19 AUG 2020 12:03

---

PC Open Date & Time

19 AUG 2020 12:00

---

PC Close Date & Time

20 AUG 2020 11:59

---

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**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

13 AUG 2020 12:17

PC Open Date & Time

13 AUG 2020 11:48

PC Close Date & Time

13 AUG 2020 14:18

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**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

13 AUG 2020 15:14

PC Open Date & Time

13 AUG 2020 15:13

PC Close Date & Time

14 AUG 2020 11:59



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**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

14 AUG 2020 12:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:46

**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

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**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

16 AUG 2020 12:02

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

**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

17 AUG 2020 12:25

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:46

**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

18 AUG 2020 12:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:46

**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

19 AUG 2020 12:03

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**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 ☐

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 12:18
PC Open Date & Time	13 AUG 2020 11:48
PC Close Date & Time	13 AUG 2020 14:18



US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**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 ☐

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 15:15
PC Open Date & Time	13 AUG 2020 15:13
PC Close Date & Time	14 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**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

50 of 1806

EAB) (1725)

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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)

52 of 1806

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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

54 of 1806

EAB) (1725)

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:26
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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 ☒

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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

60 of 1806

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US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:03
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3372110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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)	15 SEP 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 09:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3372110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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



US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3372110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 SEP 2020

Collection time (00:00-23:59)

10:04 (24 HR)

Collection date and time (derived)

15 SEP 2020 10:04

US3372110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Collection date (dd MMM yyyy)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:02	15 SEP 2020 10:02
Nasopharyngeal Swab 2	No		

US3372110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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

US3372110

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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

US3372110

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3372110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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

US3372110

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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) \_\_\_\_\_

US3372110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

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.*

US3372110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 OCT 2020

Collection time (00:00-23:59)

11:06 (24 HR)

Collection date and time (derived)

08 OCT 2020 11:06

US3372110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

<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	15 OCT 2020 12:01:18
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59



US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 05:33:20

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 12:01:15
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 00:02:35
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 03:26:15
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

24 NOV 2020 02:29:37

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	28 NOV 2020 03:26:01
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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	05 DEC 2020 06:33:59
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 DEC 2020 00:05:38
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

21 DEC 2020 12:02:05

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

26 DEC 2020 03:59:21

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

02 JAN 2021 03:33:20

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

09 JAN 2021 00:48:13

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 12:07:22

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 04:05:51

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

30 JAN 2021 02:38:24

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 08:04:10
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 05:03:37
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 13:00:30

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

27 FEB 2021 11:33:03

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

06 MAR 2021 02:50:13

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

15 MAR 2021 12:30:49

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

22 MAR 2021 12:19:17

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

27 MAR 2021 04:02:40

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 05:16:56

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

10 APR 2021 00:09:21

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 02:28:01

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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

24 APR 2021 03:27:03

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 05:43:15

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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="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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 376

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 474

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

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

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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°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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 600

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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06 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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13 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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 <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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

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29 JUN 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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06 JUL 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

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09 JUL 2022 00:01

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13 JUL 2022 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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20 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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10 AUG 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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27 AUG 2022 00:01

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31 AUG 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59



US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

**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 ☐

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3372110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

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"/>

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

**US3372110**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:38:46**

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		06 MAR 2021 02:50:26

US3372110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments



US3372110

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 17:49:42

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3372110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 20:08:20

Generated On: 11 Aug 2021 22:38:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:15 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 09:15
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 17:49:42

Generated On: 11 Aug 2021 22:38:46

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.*



US3372110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 17:49:42

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

08:58 (24 HR)

Collection date and time (derived)

09 MAR 2021 08:58

US3372110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 15:50:06

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 15:50:06

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3372110**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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*

**US3372110**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3372110**

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

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:38:46**

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

**US3372110**

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

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

**Generated On: 11 Aug 2021 22:38:46**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3372110

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

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

Visit date (dd MMM yyyy)	19 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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US3372110

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

Form: Unblinding

Data signed: (b) (4) 17 Mar 2021 17:49:42

Generated On: 11 Aug 2021 22:38:46

Date of updated informed consent ( <i>dd MMM yyyy</i> )	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3372110

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3372110

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 09:09
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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 <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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	

US3372110

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

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.*

US3372110

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 11:47 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 11:47

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

US3372110

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

19 JAN 2021 08:56



US3372110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00 - 23:59)

08:54

Collection Date and Time (derived)

19 JAN 2021 08:54

US3372110

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 23:05:47

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3372110

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3372110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

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)	16 FEB 2021
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

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)	16 FEB 2021
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 09:45
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3372110

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:29:13

Generated On: 11 Aug 2021 22:38:46

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.*



US3372110

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Mar 2021 16:29:13

Generated On: 11 Aug 2021 22:38:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 09:15

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

US3372110

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:50:22

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:50:22

Generated On: 11 Aug 2021 22:38:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3372110

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 21:50:22

Generated On: 11 Aug 2021 22:38:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372110

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	OLD57

US3372110

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:15 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 09:15
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372110

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

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.*

US3372110

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	08:58 (24 HR)
Collection date and time (derived)	09 MAR 2021 08:58



US3372110

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 01:40:11

Generated On: 11 Aug 2021 22:38:46

AEID

Adverse event

ACUTE SINUSITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

4 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

313 of 1806

EAB) (1725)

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 01:40:11

Generated On: 11 Aug 2021 22:38:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Apr 2021 01:40:11

Generated On: 11 Aug 2021 22:38:46

AEID	
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	31 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

315 of 1806

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Apr 2021 01:40:11

Generated On: 11 Aug 2021 22:38:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

318 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>



US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

320 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	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)	24 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication TESTOSTERONE INJECTIONS

Prophylaxis Yes ☐  
No ☒

Indication LOW TESTOSTERONE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

322 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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 checked="" type="radio"/>
	804	<input type="radio"/>

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC SINUSITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

324 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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"/>

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SINUS INFECTION

Dose per administration 250

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)

326 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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)		08 SEP 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	



US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE SINUSITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 1806

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 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)		10 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3372110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 23:05:46

Generated On: 11 Aug 2021 22:38:46

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3372110

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 15:36:43

Generated On: 11 Aug 2021 22:38:46

---

Date of dosing discontinuation (dd MMM yyyy) 15 SEP 2020

---

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 #3 POSITIVE FOR COVID 19

---

US3372110

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:38:46

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 ☐

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

SAEID	USA-US056-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

SAEID	USA-US056-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 21:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

SAEID	USA-US056-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/DEC/2020 03:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Mar 2021 16:30:43

Generated On: 11 Aug 2021 22:38:46

SAEID	USA-US056-2020-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/MAR/2021 15:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3372110 (Prod: Palm Beach Research Center)

**US3372110**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:38:46**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'US3372110'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:19:52

**US3372110**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:03:59

**US3372110**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:19:53

**US3372110**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:03:59

**US3372110**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'SCRN'	System	13 Aug 2020 15:03:59

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:19:54



**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '52'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'YEARS'	System	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '52'	System	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24



**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

**US3372110**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:38:46**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:04:24

US3372110

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Aug 2020'	System	13 Aug 2020 15:05:01



**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2020'	System	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:01

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:19:53

**US3372110**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:38:46**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'I'	System	13 Aug 2020 15:06:46



**US3372110**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:38:46**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:46

**US3372110**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:38:46**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 17:14:47

US3372110

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:38:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:38:54
Data point term sent to Coder	System	02 Oct 2020 18:37:29
User entered 'hypertension'	Peter Jacob (b) (4)	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2016'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:37:20



**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2016'	System	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2016'	System	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:37:20

**US3372110**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:37:20

US3372110

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:47
Data point term sent to Coder	System	02 Oct 2020 18:40:36
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '24 Jul 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:40:18



**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jul 2020'	System	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2020'	System	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:18

**US3372110**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:18

US3372110

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Investigations, HLGTT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:41:48
Data point term sent to Coder	System	02 Oct 2020 18:40:37
User entered 'low testosterone'	Peter Jacob (b) (4)	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2010'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:40:35



**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2010'	System	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2010'	System	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:35

**US3372110**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:35



US3372110

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:42:49
Data point term sent to Coder	System	02 Oct 2020 18:41:38
User entered 'chronic sinusitis'	Peter Jacob (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2010'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2010'	System	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2010'	System	02 Oct 2020 18:40:44



**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:44

**US3372110**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered empty.	System	02 Oct 2020 18:40:44

US3372110

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinuplasty, LLT: Balloon sinuplasty - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:50:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 10:50:49
Data point term sent to Coder	System	02 Oct 2020 18:46:51
User entered 'sinus ostial dilation'	Peter Jacob (b) (4)	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1998'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1998'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:46:09



**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1998'	System	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1998'	System	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1998'	System	02 Oct 2020 18:46:09

**US3372110**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1998'	System	02 Oct 2020 18:46:09

US3372110

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus polyp, LLT: Sinus polyp - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:53
Data point term sent to Coder	System	02 Oct 2020 18:47:52
User entered 'removal of sinus polyps'	Peter Jacob (b) (4)	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:47:31



**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2018'	System	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2018'	System	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2018'	System	02 Oct 2020 18:47:31

**US3372110**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2018'	System	02 Oct 2020 18:47:31

US3372110

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of face, neck and jaw congenital, PT: Cleft lip, LLT: Cleft lip - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:53:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:53:50
Data point term sent to Coder	System	02 Oct 2020 18:53:11
User entered 'cleft lip'	Peter Jacob (b) (4)	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1970'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:53:03



**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1970'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1970'	System	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1970'	System	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1970'	System	02 Oct 2020 18:53:03

**US3372110**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1970'	System	02 Oct 2020 18:53:03



US3372110

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Lip therapeutic procedures, PT: Cleft lip repair, LLT: Cleft lip repair - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
Data point term sent to Coder	System	02 Oct 2020 18:56:18
User entered 'cleft lip repair'	Peter Jacob (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1970'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 1970'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1970'	System	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1970'	System	02 Oct 2020 18:55:20



**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 1970'	System	02 Oct 2020 18:55:20

**US3372110**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '1970'	System	02 Oct 2020 18:55:20

US3372110

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:38:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus polyp, LLT: Sinus polyp - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 18:56:50
Data point term sent to Coder	System	02 Oct 2020 18:56:19
User entered 'sinus polyps'	Peter Jacob (b) (4)	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 18:55:57



**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2018'	System	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2018'	System	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'Jan 2018'	System	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:38:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '2018'	System	02 Oct 2020 18:55:57

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:33:55

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:33:55

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:06'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered '13 Aug 2020 10:06'	System	18 Aug 2020 22:33:55



**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '183.4' cm	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:33:55
DataPoint set to visible.	(b) (4) System	13 Aug 2020 15:06:46

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '117.8' kg	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:33:55
DataPoint set to visible.	(b) (4) System	13 Aug 2020 15:06:46

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
Amendment Manager: User entered '35.02246'	System	16 Sep 2020 23:54:49
User entered '35.0'	System	18 Aug 2020 22:33:55
DataPoint set to visible.	System	13 Aug 2020 15:06:46

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'kg/m2'	System	18 Aug 2020 22:33:55
DataPoint set to visible.	System	13 Aug 2020 15:06:46

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:16:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:02:45
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 16:02:31
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:32:57
User entered '36.3' C	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:33:55

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty; reason for change Data Entry Error	(b) (4)	29 Sep 2020 16:02:45
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
	(b) (4)	

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 16:02:45
User entered '75'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
	(b) (4)	



**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'bpm'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 16:02:45
User entered '16'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
	(b) (4)	

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'breaths/min'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 16:02:45
User entered '142'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
	(b) (4)	

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'mmHg'	System	18 Aug 2020 22:33:55

US3372110

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 16:02:45
User entered '88'	Peter Jacob (b) (4)	18 Aug 2020 22:33:55
	(b) (4)	

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User entered 'mmHg'	System	18 Aug 2020 22:33:55

**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34



**US3372110**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34

**US3372110**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:34:43

US3372110

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:32:09
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 13:48:38
User entered '13 Aug 2020'	Peter Jacob (b) (4)	18 Aug 2020 22:34:43
	(b) (4)	

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31



US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	Peter Jacob (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	Peter Jacob (b) (4)	18 Aug 2020 22:35:31

**US3372110**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:38:46**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Lawyer works in office environment with approx 100 other employees'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:35:31



**US3372110**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:38:46**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	Peter Jacob (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	Peter Jacob (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

**US3372110**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:38:46**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31

US3372110

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:33:34
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:35:31



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:24

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:24

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:05:24

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'VISIT1'	System	13 Aug 2020 15:05:24

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:05:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:05:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 14:59:35
User entered '103567' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 14:59:35

US3372110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:46

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:04



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:38:46**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:04

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:38:46**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:04

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:38:46**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:04

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:38:46**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:06:04

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:16:02
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:27
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:10
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:16:02
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:27
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:10
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:06'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '13 Aug 2020 10:06'	System	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '36.3' C	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '75'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'bpm'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'breaths/min'	System	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '142'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	18 Aug 2020 22:42:03

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '88'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	18 Aug 2020 22:42:03



US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:16:02
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:27
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 14:58:10
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:32:49
User entered '183.4' cm	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:03

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 14:58:10
User entered '117.8' kg	Peter Jacob (b) (4)	18 Aug 2020 22:42:03
	(b) (4)	

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '12:59'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '13 Aug 2020 12:59'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:26



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '77'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'bpm'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'breaths/min'	System	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '134'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	18 Aug 2020 22:42:26



US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '90'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:26

US3372110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	18 Aug 2020 22:42:26

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:42:53

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:42:53

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 15:32:14



US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '11:28'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '13 Aug 2020 11:28'	System	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Aug 2020 15:32:14

US3372110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'ONCE'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:43:07

US3372110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:07



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:51'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:07

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '13 Aug 2020 10:51'	System	18 Aug 2020 22:43:07

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:51'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '13 Aug 2020 10:51'	System	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15



**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	18 Aug 2020 22:43:15

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	18 Aug 2020 22:43:15

US3372110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	18 Aug 2020 22:43:19

**US3372110**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	18 Aug 2020 22:43:19

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:10:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb' User entered 'Yes (Y)'	System	13 Aug 2020 16:17:53
	System	13 Aug 2020 16:17:53

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:11:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb' User entered '97.8'	System	13 Aug 2020 16:17:53
	System	13 Aug 2020 16:17:53



US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:42', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb' User entered 'No (N)'	System	13 Aug 2020 16:17:53
	System	13 Aug 2020 16:17:53

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09c88ba0-c313-4cc7-9fdd-ac6cec607aeb' User entered '13 Aug 2020 12:17'	System	13 Aug 2020 16:17:53
	System	13 Aug 2020 16:17:53

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:13:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered 'Yes (Y)'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:13:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered '97.4'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:04', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered 'No (N)'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '35f603e1-271a-40ec-a2e0-3efa6861a0be' User entered '13 Aug 2020 15:14'	System	13 Aug 2020 19:14:14
	System	13 Aug 2020 19:14:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d' User entered 'Yes (Y)'	System	14 Aug 2020 16:00:50
	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:36', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d' User entered '97.5'	System	14 Aug 2020 16:00:50
	System	14 Aug 2020 16:00:50

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:40', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d'	System	14 Aug 2020 16:00:50
User entered 'No (N)'	System	14 Aug 2020 16:00:50

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '78d11f08-e9f7-4d50-9244-ef5c87443d0d' User entered '14 Aug 2020 12:00'	System	14 Aug 2020 16:00:50
	System	14 Aug 2020 16:00:50



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b' User entered 'Yes (Y)'	System	15 Aug 2020 16:00:56
	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b' User entered '97.4'	System	15 Aug 2020 16:00:56
	System	15 Aug 2020 16:00:56

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered 'No (N)'	System	15 Aug 2020 16:00:56

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:53', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f7c1e6ec-d248-4fa6-af07-e603adf2d89b'	System	15 Aug 2020 16:00:56
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 16:00:56

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:01:53', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7' User entered 'Yes (Y)'	System	16 Aug 2020 16:02:11
	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7' User entered '97.3'	System	16 Aug 2020 16:02:11
	System	16 Aug 2020 16:02:11

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered 'No (N)'	System	16 Aug 2020 16:02:11

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a0e538bc-2d7d-40b7-aafe-20a7882f06d7'	System	16 Aug 2020 16:02:11
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:11

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d' User entered 'Yes (Y)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d' User entered '97.4'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d' User entered 'No (N)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:31', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2cc96e97-ecd9-4b64-b10d-e815f579ad1d' User entered '17 Aug 2020 12:25'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14



US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:29', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934' User entered 'Yes (Y)'	System	18 Aug 2020 16:08:44
	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934' User entered '97.0'	System	18 Aug 2020 16:08:44
	System	18 Aug 2020 16:08:44

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered 'No (N)'	System	18 Aug 2020 16:08:44

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:42', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'dcf76ff5-ae49-4d85-a3b0-49e04fc5f934'	System	18 Aug 2020 16:08:44
User entered '18 Aug 2020 12:08'	System	18 Aug 2020 16:08:44

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:02:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf' User entered 'Yes (Y)'	System	19 Aug 2020 16:03:10
	System	19 Aug 2020 16:03:10



US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:02:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf' User entered '97.3'	System	19 Aug 2020 16:03:10
	System	19 Aug 2020 16:03:10

US3372110

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf' User entered 'No (N)'	System	19 Aug 2020 16:03:10
	System	19 Aug 2020 16:03:10

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0fb49390-1a09-43d2-b6f4-8741898350cf' User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:10
	System	19 Aug 2020 16:03:10

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75' User entered 'None (1)'	System	13 Aug 2020 16:17:40
	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'No (N)'	System	13 Aug 2020 16:17:40



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'No (N)'	System	13 Aug 2020 16:17:40

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:16:21', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered 'None (1)'	System	13 Aug 2020 16:17:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:33', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a4b56961-eff9-47c6-b1dc-b5e86958ca75'	System	13 Aug 2020 16:17:40
User entered '13 Aug 2020 12:17'	System	13 Aug 2020 16:17:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'None (1)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:31', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256' User entered 'No (N)'	System	13 Aug 2020 19:14:47
	System	13 Aug 2020 19:14:47



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'No (N)'	System	13 Aug 2020 19:14:47

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered 'None (1)'	System	13 Aug 2020 19:14:47

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3704d3f4-5d5a-4b3c-922a-225fe5b9e256'	System	13 Aug 2020 19:14:47
User entered '13 Aug 2020 15:14'	System	13 Aug 2020 19:14:47

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:49', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202' User entered 'None (1)'	System	14 Aug 2020 16:01:07
	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'No (N)'	System	14 Aug 2020 16:01:07



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:55', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202'	System	14 Aug 2020 16:01:07
User entered 'No (N)'	System	14 Aug 2020 16:01:07

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:00:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202' User entered 'None (1)'	System	14 Aug 2020 16:01:07
	System	14 Aug 2020 16:01:07

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'ece591e0-2ac0-458d-a7e2-d52cba15d202' User entered '14 Aug 2020 12:01'	System	14 Aug 2020 16:01:07
	System	14 Aug 2020 16:01:07

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:00:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf' User entered 'None (1)'	System	15 Aug 2020 16:01:14
	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf' User entered 'No (N)'	System	15 Aug 2020 16:01:14
	System	15 Aug 2020 16:01:14



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf' User entered 'No (N)'	System	15 Aug 2020 16:01:14
	System	15 Aug 2020 16:01:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf' User entered 'None (1)'	System	15 Aug 2020 16:01:14
	System	15 Aug 2020 16:01:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '28dbea7d-041d-484e-9b5a-959c8c3dc6cf' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 16:01:14
	System	15 Aug 2020 16:01:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'None (1)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:16', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632' User entered 'No (N)'	System	16 Aug 2020 16:02:29
	System	16 Aug 2020 16:02:29



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'No (N)'	System	16 Aug 2020 16:02:29

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered 'None (1)'	System	16 Aug 2020 16:02:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '13387b13-3c5c-4e43-a515-15c155a6e632'	System	16 Aug 2020 16:02:29
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:36', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84' User entered 'None (1)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:38', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84' User entered 'No (N)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:40', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84' User entered 'No (N)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84' User entered 'None (1)'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2f8d705a-30ee-4a64-989b-cb88a59b0b84' User entered '17 Aug 2020 12:25'	System	18 Aug 2020 16:08:30
	System	18 Aug 2020 16:08:30

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'None (1)'	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5' User entered 'No (N)'	System	18 Aug 2020 16:09:01
	System	18 Aug 2020 16:09:01



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5' User entered 'No (N)'	System	18 Aug 2020 16:09:01
	System	18 Aug 2020 16:09:01

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5'	System	18 Aug 2020 16:09:01
User entered 'None (1)'	System	18 Aug 2020 16:09:01

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:08:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '072b858f-f1bc-49f2-ab31-79da769851f5' User entered '18 Aug 2020 12:08'	System	18 Aug 2020 16:09:01
	System	18 Aug 2020 16:09:01

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:08', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'None (1)'	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b' User entered 'No (N)'	System	19 Aug 2020 16:03:20
	System	19 Aug 2020 16:03:20



US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b' User entered 'No (N)'	System	19 Aug 2020 16:03:20
	System	19 Aug 2020 16:03:20

US3372110

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b'	System	19 Aug 2020 16:03:20
User entered 'None (1)'	System	19 Aug 2020 16:03:20

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '3379b287-5175-40a5-8218-24bcf81a000b' User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:20
	System	19 Aug 2020 16:03:20

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:17:56', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24



US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:04', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:07', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'None (0)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196' User entered 'No (N)'	System	13 Aug 2020 16:18:24
	System	13 Aug 2020 16:18:24

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T12:18:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd935fe0d-ef69-4937-a573-372bff4e0196'	System	13 Aug 2020 16:18:24
User entered '13 Aug 2020 12:18'	System	13 Aug 2020 16:18:24

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 11:48'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 14:18'	System	13 Aug 2020 15:32:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:54', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:14:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:03', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'None (0)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered 'No (N)'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-13T15:15:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'b84d1c01-7135-4a94-99df-5082615ff8c8' User entered '13 Aug 2020 15:15'	System	13 Aug 2020 19:15:17
	System	13 Aug 2020 19:15:17

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '13 Aug 2020 15:13'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 2'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:14', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:21', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'None (0)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered 'No (N)'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-14T12:01:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '29c0ea73-5a9d-4b44-a803-eb4d8e8823d9' User entered '14 Aug 2020 12:01'	System	14 Aug 2020 16:01:40
	System	14 Aug 2020 16:01:40

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 3'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:20', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'None (0)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:27', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered 'No (N)'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-15T12:01:30', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a87db230-b229-4c14-a0e2-2945aeef9ae0' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 16:01:34
	System	15 Aug 2020 16:01:34

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 15:32:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 4'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:34', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25' User entered 'None (0)'	System	16 Aug 2020 16:02:55
	System	16 Aug 2020 16:02:55

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25' User entered 'None (0)'	System	16 Aug 2020 16:02:55
	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:39', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25' User entered 'None (0)'	System	16 Aug 2020 16:02:55
	System	16 Aug 2020 16:02:55

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:41', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25' User entered 'None (0)'	System	16 Aug 2020 16:02:55
	System	16 Aug 2020 16:02:55

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:43', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'None (0)'	System	16 Aug 2020 16:02:55

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25' User entered 'None (0)'	System	16 Aug 2020 16:02:55
	System	16 Aug 2020 16:02:55



US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:48', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered 'No (N)'	System	16 Aug 2020 16:02:55

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-16T12:02:52', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '40faa101-9516-4b13-b680-732b3106dc25'	System	16 Aug 2020 16:02:55
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 16:02:55

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 5'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:49', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:55', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31



US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:25:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:01', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'None (0)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered 'No (N)'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-17T12:26:10', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0d069e12-44cd-4212-9164-406b3dddfcd2' User entered '17 Aug 2020 12:26'	System	18 Aug 2020 16:08:31
	System	18 Aug 2020 16:08:31

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 6'	System	13 Aug 2020 15:32:14



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:06', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:14', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:19', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'None (0)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered 'No (N)'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-18T12:09:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '6e46eb69-0088-42e2-9968-e152554a3249' User entered '18 Aug 2020 12:09'	System	18 Aug 2020 16:09:29
	System	18 Aug 2020 16:09:29



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 7'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:23', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:25', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42



**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:29', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388' User entered 'None (0)'	System	19 Aug 2020 16:03:42
	System	19 Aug 2020 16:03:42

US3372110

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:38:46

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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered 'No (N)'	System	19 Aug 2020 16:03:42

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-08-19T12:03:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c1a592a1-30ed-4172-9fc1-c113bf07a388'	System	19 Aug 2020 16:03:42
User entered '19 Aug 2020 12:03'	System	19 Aug 2020 16:03:42

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:38:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 15:32:14

**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 18:24:18

**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '20 Aug 2020'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 18:24:18

**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 18:24:18



**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 18:24:18
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Aug 2020 18:24:27

**US3372110**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	21 Aug 2020 18:24:27

**US3372110**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
User entered 'No (N)'	(b) (4)	
	Peter Jacob (b) (4)	23 Sep 2020 19:47:57
	(b) (4)	

US3372110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
User entered empty.	(b) (4)	
	Peter Jacob (b) (4)	23 Sep 2020 19:47:57
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Peter Jacob (b) (4)	23 Sep 2020 19:51:53
User entered empty.	(b) (4)	
	Peter Jacob (b) (4)	23 Sep 2020 19:47:57
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:57

**US3372110**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 20:04:05



**US3372110**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	03 Sep 2020 20:04:05

**US3372110**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 20:04:25

**US3372110**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '3 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 20:04:25

**US3372110**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	03 Sep 2020 20:04:25

US3372110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	03 Sep 2020 20:04:28

**US3372110**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	03 Sep 2020 20:04:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:48:38



**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:48:38

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:48:38

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'VISIT2'	System	15 Sep 2020 13:48:38

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '09:16'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '15 Sep 2020 09:16'	System	23 Sep 2020 19:36:53



US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '84'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'bpm'	System	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '17'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'breaths/min'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '123'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53



US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	23 Sep 2020 19:36:53

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '88'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'mmHg'	System	23 Sep 2020 19:36:53

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	23 Sep 2020 19:37:28



**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	23 Sep 2020 19:37:28

US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:37:28



US3372110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	23 Sep 2020 19:37:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:48

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:37:48

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 20:29:28
Query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' answered with 'patient is asymptomatic ' (Site from DM).	Peter Jacob (b) (4) (b) (4)	05 Oct 2020 15:21:54
User opened query 'Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:41:55
User entered 'Confirmed COVID-19 (COVID)'	(b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:49:15



US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:49:15

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:49:15

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Sep 2020 13:49:15

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:49:15

US3372110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Sep 2020 13:49:15

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Sep 2020 13:49:15

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:10:49



**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:10:49

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:04' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	02 Oct 2020 19:10:52
User entered '10:02'	(b) (4)	
	Peter Jacob (b) (4)	02 Oct 2020 19:10:49
	(b) (4)	

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '15 Sep 2020 10:04'	System	02 Oct 2020 19:10:52
User entered '15 Sep 2020 10:02'	System	02 Oct 2020 19:10:49

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10:02'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '15 Sep 2020 10:02'	System	02 Oct 2020 19:11:04



**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	02 Oct 2020 19:11:04

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	21 Sep 2020 19:22:28

**US3372110**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	21 Sep 2020 19:22:28

**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27



**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	23 Sep 2020 19:47:27

**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:27

**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Sep 2020 19:47:34

**US3372110**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	23 Sep 2020 19:47:34

**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:37

**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:37

**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:37

**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:37



**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:52:51

**US3372110**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	08 Oct 2020 14:52:51

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:42

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:42

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:42

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:42

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:52:58

**US3372110**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	08 Oct 2020 14:52:58



**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	08 Oct 2020 14:53:10

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	15 Oct 2020 21:08:51
User entered '8 Oct 2020'	(b) (4)	
	Elena Acosta (b) (4)	08 Oct 2020 14:53:10
	(b) (4)	

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Clinic (Clinic)'	Elena Acosta (b) (4)	08 Oct 2020 14:53:10

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'VISIT3'	System	08 Oct 2020 14:53:10

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Oct 2020 21:08:55



**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:08:55



**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered empty.	System	15 Oct 2020 21:08:55

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25

US3372110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:04

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:09:04

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:09:15



**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '08 Oct 2020'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:09:15

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '11:06'	(b) (4) Peter Jacob (b) (4) (b) (4)	15 Oct 2020 21:09:15

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered '08 Oct 2020 11:06'	System	15 Oct 2020 21:09:15

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	15 Oct 2020 21:09:19

**US3372110**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	15 Oct 2020 21:09:19

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 64'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

[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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28'	System	15 Oct 2020 16:01:59
User entered 'No (N)'	System	15 Oct 2020 16:01:59

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28'	System	15 Oct 2020 16:01:59
User entered 'No (N)'	System	15 Oct 2020 16:01:59



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-15T12:01:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '51cdaf9f-8df1-4be1-a33c-f1721e3fee28' User entered '15 Oct 2020 12:01:18'	System	15 Oct 2020 16:01:59
	System	15 Oct 2020 16:01:59

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 71'	System	13 Aug 2020 15:32:14

US3372110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:46

[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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0' User entered 'No (N)'	System	20 Oct 2020 09:33:26
	System	20 Oct 2020 09:33:26

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0'	System	20 Oct 2020 09:33:26
User entered 'No (N)'	System	20 Oct 2020 09:33:26

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-20T05:33:20', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd60b6158-3876-4ef4-9c02-0c855dae74a0' User entered '20 Oct 2020 05:33:20'	System	20 Oct 2020 09:33:26
	System	20 Oct 2020 09:33:26

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 15:32:14



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 78'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:00:44', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'No (N)'	System	29 Oct 2020 16:02:12

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:00:50', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'Yes (Y)'	System	29 Oct 2020 16:02:12

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:01:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0'	System	29 Oct 2020 16:02:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 16:02:12

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-10-29T12:01:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '44681d75-9fdd-4247-8896-ff3c78cf40c0' User entered '29 Oct 2020 12:01:15'	System	29 Oct 2020 16:02:12
	System	29 Oct 2020 16:02:12

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 15:32:14



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 92'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:01:46', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4' User entered 'No (N)'	System	10 Nov 2020 05:02:46
	System	10 Nov 2020 05:02:46

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:01:57', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4'	System	10 Nov 2020 05:02:46
User entered 'Yes (Y)'	System	10 Nov 2020 05:02:46

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:02:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4'	System	10 Nov 2020 05:02:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 05:02:46

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-10T00:02:35', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '353448ef-4fb2-4308-bc81-6ed248a06bb4' User entered '10 Nov 2020 00:02:35'	System	10 Nov 2020 05:02:46
	System	10 Nov 2020 05:02:46

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered 'Day 99'	System	13 Aug 2020 15:32:14



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:25:58', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da' User entered 'No (N)'	System	17 Nov 2020 08:26:19
	System	17 Nov 2020 08:26:19

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:26:07', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da' User entered 'No (N)'	System	17 Nov 2020 08:26:19
	System	17 Nov 2020 08:26:19

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-17T03:26:15', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0ab64f89-8489-43ee-aac3-0160013b51da' User entered '17 Nov 2020 03:26:15'	System	17 Nov 2020 08:26:19
	System	17 Nov 2020 08:26:19

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:37:08
Data entry locked.	System	13 Aug 2020 15:32:14
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 15:32:14

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:28', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1' User entered 'No (N)'	System	24 Nov 2020 07:29:42

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:32', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1' User entered 'No (N)'	System	24 Nov 2020 07:29:42



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-24T02:29:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '09eabffa-50b3-4f74-9f1b-f5f84c737ac1' User entered '24 Nov 2020 02:29:37'	System	24 Nov 2020 07:29:42
	System	24 Nov 2020 07:29:42

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-28T03:25:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5f172057-654b-4cdf-a5f7-8f90deef660f' User entered 'No (N)'	System	28 Nov 2020 08:26:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-28T03:25:56', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5f172057-654b-4cdf-a5f7-8f90deef660f' User entered 'No (N)'	System	28 Nov 2020 08:26:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-11-28T03:26:01', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5f172057-654b-4cdf-a5f7-8f90deef660f' User entered '28 Nov 2020 03:26:01'	System	28 Nov 2020 08:26:04
	System	28 Nov 2020 08:26:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-05T06:33:45', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0979b559-d60b-4b60-8d5d-a5b648a88f61'	System	05 Dec 2020 10:34:01
User entered 'No (N)'	System	05 Dec 2020 10:34:01

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-05T06:33:49', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0979b559-d60b-4b60-8d5d-a5b648a88f61'	System	05 Dec 2020 10:34:01
User entered 'No (N)'	System	05 Dec 2020 10:34:01

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-05T06:33:59', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '0979b559-d60b-4b60-8d5d-a5b648a88f61' User entered '05 Dec 2020 06:33:59'	System	05 Dec 2020 10:34:01

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-12T00:05:11', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '199ead86-f44a-49c6-9ea4-0706b6cedf05'	System	12 Dec 2020 05:05:41
User entered 'Yes (Y)'	System	12 Dec 2020 05:05:41

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-12T00:05:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '199ead86-f44a-49c6-9ea4-0706b6cedf05'	System	12 Dec 2020 05:05:41
User entered 'No (N)'	System	12 Dec 2020 05:05:41

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-12T00:05:23', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '199ead86-f44a-49c6-9ea4-0706b6cedf05'	System	12 Dec 2020 05:05:41
User entered 'No (N)'	System	12 Dec 2020 05:05:41

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-12T00:05:33', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '199ead86-f44a-49c6-9ea4-0706b6cedf05'	System	12 Dec 2020 05:05:41
User entered 'No (N)'	System	12 Dec 2020 05:05:41

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-12T00:05:38', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '199ead86-f44a-49c6-9ea4-0706b6cedf05' User entered '12 Dec 2020 00:05:38'	System	12 Dec 2020 05:05:41
	System	12 Dec 2020 05:05:41

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-21T12:01:56', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '10db8073-a510-43f9-9de5-a2fc87b0152e' User entered 'No (N)'	System	21 Dec 2020 17:02:09
	System	21 Dec 2020 17:02:09

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-21T12:02:02', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '10db8073-a510-43f9-9de5-a2fc87b0152e' User entered 'No (N)'	System	21 Dec 2020 17:02:09
	System	21 Dec 2020 17:02:09

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-21T12:02:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '10db8073-a510-43f9-9de5-a2fc87b0152e' User entered '21 Dec 2020 12:02:05'	System	21 Dec 2020 17:02:09
	System	21 Dec 2020 17:02:09

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-26T03:59:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '27774bc7-293f-46b5-a5f3-59e302c2a1ea' User entered 'No (N)'	System	26 Dec 2020 08:59:24
	System	26 Dec 2020 08:59:24

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-26T03:59:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '27774bc7-293f-46b5-a5f3-59e302c2a1ea' User entered 'No (N)'	System	26 Dec 2020 08:59:24
	System	26 Dec 2020 08:59:24



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2020-12-26T03:59:21', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '27774bc7-293f-46b5-a5f3-59e302c2a1ea' User entered '26 Dec 2020 03:59:21'	System	26 Dec 2020 08:59:24
	System	26 Dec 2020 08:59:24

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-02T03:33:07', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f798164f-719f-4e25-94bf-a4f6b680a5ae'	System	02 Jan 2021 08:33:23
User entered 'No (N)'	System	02 Jan 2021 08:33:23

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-02T03:33:12', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f798164f-719f-4e25-94bf-a4f6b680a5ae'	System	02 Jan 2021 08:33:23
User entered 'No (N)'	System	02 Jan 2021 08:33:23

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-02T03:33:20', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'f798164f-719f-4e25-94bf-a4f6b680a5ae' User entered '02 Jan 2021 03:33:20'	System	02 Jan 2021 08:33:23
	System	02 Jan 2021 08:33:23

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-09T00:47:58', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8b8d1164-6e09-43d5-a314-25913c1254e6'	System	09 Jan 2021 05:48:18
User entered 'No (N)'	System	09 Jan 2021 05:48:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-09T00:48:04', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8b8d1164-6e09-43d5-a314-25913c1254e6'	System	09 Jan 2021 05:48:18
User entered 'No (N)'	System	09 Jan 2021 05:48:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-09T00:48:13', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8b8d1164-6e09-43d5-a314-25913c1254e6' User entered '09 Jan 2021 00:48:13'	System	09 Jan 2021 05:48:18
	System	09 Jan 2021 05:48:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-18T12:07:09', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd4fb025c-b67a-4e6e-acd1-108e0df000fe' User entered 'No (N)'	System	18 Jan 2021 17:07:25
	System	18 Jan 2021 17:07:25

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-18T12:07:17', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd4fb025c-b67a-4e6e-acd1-108e0df000fe' User entered 'No (N)'	System	18 Jan 2021 17:07:25

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-18T12:07:22', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'd4fb025c-b67a-4e6e-acd1-108e0df000fe' User entered '18 Jan 2021 12:07:22'	System	18 Jan 2021 17:07:25
	System	18 Jan 2021 17:07:25

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-23T04:05:38', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2801470b-48f8-4996-9d23-d1d9cb6f4c5e'	System	23 Jan 2021 09:05:54
User entered 'No (N)'	System	23 Jan 2021 09:05:54

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-23T04:05:46', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2801470b-48f8-4996-9d23-d1d9cb6f4c5e'	System	23 Jan 2021 09:05:54
User entered 'No (N)'	System	23 Jan 2021 09:05:54



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-23T04:05:51', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2801470b-48f8-4996-9d23-d1d9cb6f4c5e' User entered '23 Jan 2021 04:05:51'	System	23 Jan 2021 09:05:54
	System	23 Jan 2021 09:05:54

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-30T02:38:10', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8eb195da-bee0-420d-987b-ed78dffcc9a'	System	30 Jan 2021 07:38:28
User entered 'No (N)'	System	30 Jan 2021 07:38:28

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-30T02:38:18', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8eb195da-bee0-420d-987b-edc78dffc9a'	System	30 Jan 2021 07:38:28
User entered 'No (N)'	System	30 Jan 2021 07:38:28

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-01-30T02:38:24', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '8eb195da-bee0-420d-987b-edc78dffc9a' User entered '30 Jan 2021 02:38:24'	System	30 Jan 2021 07:38:28
	System	30 Jan 2021 07:38:28

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-06T08:04:01', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '1ae75723-cfd9-46df-bb6b-d0f63911754f' User entered 'No (N)'	System	06 Feb 2021 13:04:13

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-06T08:04:05', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '1ae75723-cfd9-46df-bb6b-d0f63911754f' User entered 'No (N)'	System	06 Feb 2021 13:04:13

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-06T08:04:10', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '1ae75723-cfd9-46df-bb6b-d0f63911754f' User entered '06 Feb 2021 08:04:10'	System	06 Feb 2021 13:04:13
	System	06 Feb 2021 13:04:13

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-13T05:03:26', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a1df6e6e-19c6-4ee3-9372-fd958f8defe5'	System	13 Feb 2021 10:03:40
User entered 'No (N)'	System	13 Feb 2021 10:03:40

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-13T05:03:32', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a1df6e6e-19c6-4ee3-9372-fd958f8defe5'	System	13 Feb 2021 10:03:40
User entered 'No (N)'	System	13 Feb 2021 10:03:40

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-13T05:03:37', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a1df6e6e-19c6-4ee3-9372-fd958f8defe5' User entered '13 Feb 2021 05:03:37'	System	13 Feb 2021 10:03:40
	System	13 Feb 2021 10:03:40

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-23T08:00:23-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '9bc1f3a5-5f8f-40d7-a42e-66489915df5c' User entered 'No (N)'	System	23 Feb 2021 13:00:37
	System	23 Feb 2021 13:00:37

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-23T08:00:27-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '9bc1f3a5-5f8f-40d7-a42e-66489915df5c'	System	23 Feb 2021 13:00:37
User entered 'No (N)'	System	23 Feb 2021 13:00:37



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-23T08:00:30-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '9bc1f3a5-5f8f-40d7-a42e-66489915df5c'	System	23 Feb 2021 13:00:37
User entered '23 Feb 2021 13:00:30'	System	23 Feb 2021 13:00:37

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-27T06:32:47-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '4657c9e2-8b38-4dc4-bffd-392c101bdf3e'	System	27 Feb 2021 11:33:05
User entered 'No (N)'	System	27 Feb 2021 11:33:05

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-27T06:32:54-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '4657c9e2-8b38-4dc4-bffd-392c101bdf3e'	System	27 Feb 2021 11:33:05
User entered 'No (N)'	System	27 Feb 2021 11:33:05

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-02-27T06:33:03-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '4657c9e2-8b38-4dc4-bffd-392c101bdf3e' User entered '27 Feb 2021 11:33:03'	System	27 Feb 2021 11:33:05
	System	27 Feb 2021 11:33:05

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-06T02:50:03-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '43e9b226-6fc6-45d4-8ae0-1460be98ee23'	System	06 Mar 2021 07:50:22
User entered 'No (N)'	System	06 Mar 2021 07:50:22

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-06T02:50:08-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '43e9b226-6fc6-45d4-8ae0-1460be98ee23'	System	06 Mar 2021 07:50:22
User entered 'No (N)'	System	06 Mar 2021 07:50:22

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-06T02:50:13-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '43e9b226-6fc6-45d4-8ae0-1460be98ee23'	System	06 Mar 2021 07:50:22
User entered '06 Mar 2021 02:50:13'	System	06 Mar 2021 07:50:22

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-15T12:30:40-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '30b5e030-1718-4aa1-866e-2c3d3797d5ca'	System	15 Mar 2021 16:30:57
User entered 'No (N)'	System	15 Mar 2021 16:30:57

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-15T12:30:44-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '30b5e030-1718-4aa1-866e-2c3d3797d5ca'	System	15 Mar 2021 16:30:57
User entered 'No (N)'	System	15 Mar 2021 16:30:57

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-15T12:30:49-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '30b5e030-1718-4aa1-866e-2c3d3797d5ca' User entered '15 Mar 2021 12:30:49'	System	15 Mar 2021 16:30:57
	System	15 Mar 2021 16:30:57

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-22T12:19:13-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c51741a7-9f1d-44e1-8252-e480c6c0684d' User entered 'No (N)'	System	22 Mar 2021 16:35:17
	System	22 Mar 2021 16:35:17

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-22T12:19:15-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c51741a7-9f1d-44e1-8252-e480c6c0684d'	System	22 Mar 2021 16:35:17
User entered 'No (N)'	System	22 Mar 2021 16:35:17



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-22T12:19:17-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'c51741a7-9f1d-44e1-8252-e480c6c0684d' User entered '22 Mar 2021 12:19:17'	System	22 Mar 2021 16:35:17
	System	22 Mar 2021 16:35:17

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-27T04:02:34-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2ccb1cfb-d9ea-4266-afd2-a23398320651'	System	27 Mar 2021 08:02:44
User entered 'No (N)'	System	27 Mar 2021 08:02:44

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-27T04:02:36-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2ccb1cfb-d9ea-4266-afd2-a23398320651'	System	27 Mar 2021 08:02:44
User entered 'No (N)'	System	27 Mar 2021 08:02:44

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-27T04:02:40-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '2ccb1cfb-d9ea-4266-afd2-a23398320651' User entered '27 Mar 2021 04:02:40'	System	27 Mar 2021 08:02:44
	System	27 Mar 2021 08:02:44

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-03T05:16:50-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a97cb4b4-158b-4f8f-996e-529c73fd600b'	System	03 Apr 2021 09:16:59
User entered 'No (N)'	System	03 Apr 2021 09:16:59

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-03T05:16:52-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a97cb4b4-158b-4f8f-996e-529c73fd600b'	System	03 Apr 2021 09:16:59
User entered 'No (N)'	System	03 Apr 2021 09:16:59

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-03T05:16:56-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a97cb4b4-158b-4f8f-996e-529c73fd600b'	System	03 Apr 2021 09:16:59
User entered '03 Apr 2021 05:16:56'	System	03 Apr 2021 09:16:59

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-10T00:09:16-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '146548a2-3b42-4c71-8167-a32e8e191dff' User entered 'No (N)'	System	10 Apr 2021 04:09:48
	System	10 Apr 2021 04:09:48

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-10T00:09:18-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '146548a2-3b42-4c71-8167-a32e8e191dff'	System	10 Apr 2021 04:09:48
User entered 'No (N)'	System	10 Apr 2021 04:09:48

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-10T00:09:21-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '146548a2-3b42-4c71-8167-a32e8e191dff'	System	10 Apr 2021 04:09:48
User entered '10 Apr 2021 00:09:21'	System	10 Apr 2021 04:09:48

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-17T02:27:54-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'fef885b1-c8df-4f6b-bc39-1271b925c43d'	System	17 Apr 2021 06:28:06
User entered 'No (N)'	System	17 Apr 2021 06:28:06

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-17T02:27:56-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'fef885b1-c8df-4f6b-bc39-1271b925c43d' User entered 'No (N)'	System	17 Apr 2021 06:28:06



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-17T02:28:01-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'fef885b1-c8df-4f6b-bc39-1271b925c43d' User entered '17 Apr 2021 02:28:01'	System	17 Apr 2021 06:28:06
	System	17 Apr 2021 06:28:06

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-24T03:26:56-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a3526bc1-d2ff-4092-935e-d4f499710b1b'	System	24 Apr 2021 07:27:08
User entered 'No (N)'	System	24 Apr 2021 07:27:08

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-24T03:26:59-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a3526bc1-d2ff-4092-935e-d4f499710b1b'	System	24 Apr 2021 07:27:08
User entered 'No (N)'	System	24 Apr 2021 07:27:08

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-04-24T03:27:03-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: 'a3526bc1-d2ff-4092-935e-d4f499710b1b' User entered '24 Apr 2021 03:27:03'	System	24 Apr 2021 07:27:08
	System	24 Apr 2021 07:27:08

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-05-01T05:43:06-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5231b689-163c-4339-b18d-5e014a6d93b4'	System	01 May 2021 09:43:18
User entered 'No (N)'	System	01 May 2021 09:43:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

Have you been exposed to someone with 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 (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-05-01T05:43:12-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5231b689-163c-4339-b18d-5e014a6d93b4'	System	01 May 2021 09:43:18
User entered 'No (N)'	System	01 May 2021 09:43:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-05-01T05:43:15-04:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '5231b689-163c-4339-b18d-5e014a6d93b4'	System	01 May 2021 09:43:18
User entered '01 May 2021 05:43:15'	System	01 May 2021 09:43:18

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:45:04



**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 05:45:04



**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 05:45:04

**US3372110**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:38:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:45:04
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 05:45:04

US3372110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:38:46

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:47:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-06T02:50:22-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '86fc961c-fb5d-42a2-8c22-58007a37d993'	System	06 Mar 2021 07:50:32
User entered 'No (N)'	System	06 Mar 2021 07:50:32

**US3372110**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:47:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4842FC53-F553-49C1-9091-E6E92E76A221)', Time: '2021-03-06T02:50:26-05:00', User OID: 'PatientReportedOutcome (US3372110)', ODM File OID: '86fc961c-fb5d-42a2-8c22-58007a37d993'	System	06 Mar 2021 07:50:32
User entered '06 Mar 2021 02:50:26'	System	06 Mar 2021 07:50:32

**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:15

**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:15

**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:15



**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:15
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:22

**US3372110**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:05:25
User entered 'I'	System	13 Jan 2021 20:03:22

**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:37

**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '14 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:37
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:37

**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:37
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:45



**US3372110**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'I'	System	13 Jan 2021 20:03:45

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:57

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '13 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	13 Jan 2021 20:03:57
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:57

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:03:57

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Jan 2021 20:04:07

**US3372110**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered '1'	System	13 Jan 2021 20:04:07

**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Feb 2021 13:41:22



**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '8 Feb 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Feb 2021 13:41:22

**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	08 Feb 2021 13:41:22

**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Danielle Theodore (b) (4)	08 Feb 2021 13:41:22
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	08 Feb 2021 13:41:31
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'I'	System	08 Feb 2021 13:41:31

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:48:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
Signature has been broken.	(b) (4) Peter Jacob (b) (4)	17 Mar 2021 15:49:12
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4) Peter Jacob (b) (4)	17 Mar 2021 15:49:12
User signature succeeded.	(b) (4) Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:48:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:48:09



**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'VISIT4'	System	09 Mar 2021 13:48:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '09:15'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered '09 Mar 2021 09:15'	System	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09



**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'bpm'	System	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'breaths/min'	System	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '154'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'mmHg'	System	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	30 Mar 2021 20:08:20
User entered '90'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:39:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'mmHg'	System	30 Mar 2021 19:39:09



**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:17

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:54:17

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:02

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:02

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered '08:58'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:55:02

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered '09 Mar 2021 08:58'	System	17 Mar 2021 15:55:02



**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 13:48:22

**US3372110**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:43:09
User entered 'I'	System	09 Mar 2021 13:48:22

**US3372110**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 15:33:03
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:50:06
User entered '13 Apr 2021'	(b) (4) Danielle Theodore (b) (4)	13 Apr 2021 15:33:03
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Apr 2021 15:33:03

**US3372110**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:50:06
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	13 Apr 2021 15:33:03
	(b) (4)	

US3372110

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 15:50:06
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	13 Apr 2021 15:33:22
	(b) (4)	

**US3372110**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 15:33:22



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:45:58

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:45:58

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:45:58

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 18:45:58

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered '0'	(b) (4) Peter Jacob (b) (4)	17 Mar 2021 15:49:42
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:27:30

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	17 Mar 2021 17:49:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Peter Jacob (b) (4)	17 Mar 2021 15:49:42
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:27:30



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02
DataPoint set to visible.	System	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02
DataPoint set to visible.	System	22 Jan 2021 18:46:25

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '09:09'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '19 Jan 2021 09:09'	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

US3372110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '76'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'bpm'	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'breaths/min'	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '140'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '89'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:38:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02
DataPoint set to visible.	System	22 Jan 2021 18:46:25



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02

US3372110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02

US3372110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:02

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered empty.	System	22 Jan 2021 19:28:02



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:06

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:28:06

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17

US3372110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

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)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mRNA-1273'	System	22 Jan 2021 19:29:17
DataPoint set to visible.	System	22 Jan 2021 18:46:25

US3372110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '11:47'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '19 Jan 2021 11:47'	System	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'ONCE'	System	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 19:29:17

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:36

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:36

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '08:56'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:36

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '19 Jan 2021 08:56'	System	22 Jan 2021 18:46:36



**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:47

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:47

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '08:54'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:47

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:38:46**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '19 Jan 2021 08:54'	System	22 Jan 2021 18:46:47

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:46:51

**US3372110**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	22 Jan 2021 18:46:51

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 13:55:02
	(b) (4)	

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 13:55:02



**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 13:55:02

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	26 Jan 2021 13:55:02

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 13:55:13
	(b) (4)	

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	26 Jan 2021 13:55:13

**US3372110**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	26 Jan 2021 13:55:13
DataPoint set to visible.	System	26 Jan 2021 13:55:13

**US3372110**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:52:45

US3372110

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	12 Mar 2021 21:10:46
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	12 Mar 2021 21:10:46
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:10:46
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	10 Mar 2021 14:52:45
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 14:52:45

**US3372110**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:52:45



**US3372110**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'OLD29'	System	10 Mar 2021 14:52:45

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:33

US3372110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:11:18
User entered '16 Feb 2021' reason for change: Data Entry Error	System	12 Mar 2021 21:11:18
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 21:10:46
User entered '9 Mar 2021'	System	10 Mar 2021 14:54:33

US3372110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	12 Mar 2021 21:11:18
User entered '08:25' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:11:18
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	10 Mar 2021 14:55:13
User entered '09:15'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '16 Feb 2021 08:25'	System	12 Mar 2021 21:11:18
User entered '9 Mar 2021 09:15'	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:12:18
User entered '36.6' C	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:33



**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '76' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 21:12:18
User entered '73'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'bpm'	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '20' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:12:18
User entered '17'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'breaths/min'	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '144' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:12:18
User entered '154'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '93' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:12:18
User entered '90'	(b) (4), (b) (6)	10 Mar 2021 14:54:33



**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '09:45' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '16 Feb 2021 09:45'	System	12 Mar 2021 21:13:27
User entered empty.	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '36.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33



**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Forehead' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '71' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'bpm'	System	12 Mar 2021 21:13:27
User entered empty.	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '18' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'breaths/min'	System	12 Mar 2021 21:13:27
User entered empty.	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '134' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	12 Mar 2021 21:13:27
User entered empty.	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '92' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:13:27
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:33



**US3372110**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	12 Mar 2021 21:13:27
User entered empty.	System	10 Mar 2021 14:54:33

**US3372110**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:36

**US3372110**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:36

US3372110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	10 Mar 2021 14:55:13
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	10 Mar 2021 14:55:13
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	10 Mar 2021 14:54:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:54

US3372110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

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)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mRNA-1273'	System	10 Mar 2021 14:54:54
DataPoint set to visible.	System	26 Jan 2021 13:55:13

US3372110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	12 Mar 2021 21:14:24
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Mar 2021 21:14:24
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 21:14:24
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	12 Mar 2021 21:10:46
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 14:54:54



US3372110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered '09:15' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:14:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 14:55:13
User entered '08:58' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 14:55:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 14:54:54
User entered '08:' (non-conformant).	(b) (4), (b) (6)	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '16 Feb 2021 09:15'	System	12 Mar 2021 21:14:24
User entered '9 Mar 2021 08:58'	System	10 Mar 2021 14:55:13
User entered '9 Mar 2021 08:.' (non-conformant).	System	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:29:13
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 14:55:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:54:54

US3372110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'ONCE'	System	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:38:46**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 14:54:54

**US3372110**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 16:50:15
	(b) (4)	

**US3372110**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	23 Feb 2021 16:50:15

**US3372110**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 16:51:40
	(b) (4)	



US3372110

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 21:14:24
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	12 Mar 2021 21:14:24
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Mar 2021 14:54:54
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered '23 Feb 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	23 Feb 2021 16:51:40

**US3372110**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 16:51:40
	(b) (4)	

**US3372110**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:38:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered empty.	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 16:51:40
	(b) (4)	

**US3372110**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:50:22
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	23 Feb 2021 16:51:47

**US3372110**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:38:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'I'	System	23 Feb 2021 16:51:47

US3372110

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Visit 04 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:48:10
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Visit 04 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with 'Data correct as is. Visits took place on same day' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:53:34
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Visit 04 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:54:26
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:08:40

US3372110

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	16 Mar 2021 16:11:41
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'According to source, data is correct' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 20:22:06
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Mar 2021 21:08:40
User entered '09 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:08:40

**US3372110**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:08:40



**US3372110**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:38:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'OLD57'	System	12 Mar 2021 21:08:40

US3372110

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User closed query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM). Query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:24:10
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:39:20
User signature succeeded.	Mira Baron (b) (4)	27 Mar 2021 15:27:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 16:30:43
	(b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '09:15'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '09 Mar 2021 09:15'	System	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27



**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '73'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'bpm'	System	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '17'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'breaths/min'	System	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '154'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '90'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:27

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered 'mmHg'	System	12 Mar 2021 21:17:27



**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23

**US3372110**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:38:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23

**US3372110**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:32

**US3372110**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:38:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:32

**US3372110**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:46

**US3372110**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:46

**US3372110**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '08:58'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:17:46

**US3372110**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:38:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:28:23
User entered '09 Mar 2021 08:58'	System	12 Mar 2021 21:17:46



**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:38:46**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:43:49
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	13 Nov 2020 20:17:49

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of CHRONIC SINUSITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:04:22
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
Query 'Per DM CLR: Please confirm if this AE is a worsening of CHRONIC SINUSITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'Data correct as is. This not a worsening of Chronic Sinusitis and it did meet AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:01:35
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of CHRONIC SINUSITIS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 06:55:22
User closed query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:04:28
Query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' answered with 'data correct as is' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:22:09

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:28:23
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 20:21:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Nov 2020 20:21:52
Data point term sent to Coder	System	13 Nov 2020 20:21:33
User entered 'Acute Sinusitis'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '4 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01



**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4) (b) (4)	01 Apr 2021 12:39:08
User entered empty.	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User entered empty.	System	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '10 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User entered empty.	System	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01



US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4) (b) (4)	01 Apr 2021 12:39:08
User entered empty.	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01



US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:54:02
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 17:44:16
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Torres (b) (4)	18 Nov 2020 17:44:06
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:23:12
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User closed query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:57:17
Query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 21:22:00
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 21:21:52
User opened query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:35:52
Query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:35:48
User opened query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:35:42
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'I'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01



US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

US3372110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User entered '0'	System	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08
User entered '1'	System	13 Nov 2020 20:21:01

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:49:08

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Mar 2021 21:09:15
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 21:05:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 21:53:14
User entered	System	16 Nov 2020 21:53:09
'USA-US056-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	16 Nov 2020 21:53:09

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User closed query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:57:56
User closed query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:49:05
Query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	10 Mar 2021 16:46:45
Query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting.' answered with 'Subject was asymptomatic' (Site from Safety).	Mary Sergalis (b) (4)	10 Mar 2021 16:30:39
User opened query 'Per MM, There are AE that could be the same event recorded with overlapping dates - please review and consider combining events into one AE that is a medical diagnosis and deleting the duplicate entry.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:31:16
User opened query 'PV Query: Per protocol section 8.1.1; if the subject has at least two systemic symptoms or one respiratory symptom along with a positive SARS-CoV-2 by RT-PCR, then this must be filed as an event through the end of the study. Please reassess if COVID-19 meets criteria for reporting.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 19:11:23
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:26:35

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1591 of 1806



US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Nov 2020 20:26:35
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 20:25:50
User entered 'Covid 19'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	27 Apr 2021 01:40:11
User closed query 'PV Query Urgent: Thank you for confirming in query response the event was asymptomatic. Please change this answer to 'No'. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:49:30
Query 'PV Query Urgent: Thank you for confirming in query response the event was asymptomatic. Please change this answer to 'No'. ' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 18:04:01
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:03:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:03:50
User opened query 'PV Query Urgent: Thank you for confirming in query response the event was asymptomatic. Please change this answer to 'No'. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:19:17
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '31 Aug 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13



US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '14 Sep 2020'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

Death

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13



US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	13 Nov 2020 20:25:13



US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:54:19
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:45:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4) (b) (4)	18 Nov 2020 17:45:21
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:10:26
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User closed query 'Per CDM-Action taken with investigational product is recorded as 'Investigational Product Withdrawn',however,no data is recorded on dosing discontinuation form. Kindly consider to verify and update data appropriately .' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 14:49:22
Query 'Per CDM-Action taken with investigational product is recorded as 'Investigational Product Withdrawn',however,no data is recorded on dosing discontinuation form. Kindly consider to verify and update data appropriately .' answered with 'data is entered' (Site from DM).	Mary Sergalis (b) (4)	10 Mar 2021 16:45:55
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		10 Mar 2021 16:34:06
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	10 Mar 2021 16:34:06
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Dec 2020 16:14:11
User opened query 'Per CDM-Action taken with investigational product is recorded as 'Investigational Product Withdrawn',however,no data is recorded on dosing discontinuation form. Kindly consider to verify and update data appropriately .' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:38:45
Query 'Per CDM-Action taken with investigational product is recorded as 'Investigational Product Withdrawn',however,no data is recorded on dosing discontinuation form.' canceled (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:38:21

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM-Action taken with investigational product is recorded as 'Investigational Product Withdrawn',however,no data is recorded on dosing discontinuation form.' (Site from DM). User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	26 Nov 2020 10:38:10
	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered 'I'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:25:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 20:25:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	13 Nov 2020 20:25:21
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:25:13
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13



US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	01 Apr 2021 12:39:08
User closed query 'PV Query: Please confirm date and results of COVID-19 testing.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please confirm date and results of COVID-19 testing.' answered with '15-SEP-2020 Positive' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 20:58:02
User opened query 'PV Query: Please confirm date and results of COVID-19 testing.' (Site from Safety).	Mary Sergalis (b) (4)	10 Mar 2021 16:44:38
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 19:10:34
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 03:57:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment was required since subject was asymptomatic' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 03:57:47
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' answered with 'subject was asymptomatic and did not require any illness visits' (Site from Safety).	Peter Jacob (b) (4)	24 Nov 2020 22:52:01
	(b) (4)	
	Peter Jacob (b) (4)	24 Nov 2020 22:51:27
	(b) (4)	

US3372110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:38:46

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:12:26
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:12:10
User entered empty.	Mary Sergalis (b) (4)	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:25:13

**US3372110**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 20:25:13

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:38:46**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:43:49
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 19:11:38

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 19:16:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:16:54
Data point term sent to Coder	System	02 Oct 2020 19:15:57
User entered 'losartan'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '50'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'un UNK 2016'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:15:30
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:15:30

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:15:30

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 19:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:23:43
Data point term sent to Coder	System	02 Oct 2020 19:23:10
User entered 'rosuvastatin'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '20'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45



US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '24 Jul 2020'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:22:45
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:22:45

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:22:45

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:22:45



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:22:45

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Oct 2020 04:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:27:48
Data point term sent to Coder	System	02 Oct 2020 19:24:11
User entered 'testosterone injections'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'low testosterone'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'I'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:06:05
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.	(b) (4), (b) (6)	11 Nov 2020 14:46:06
' answered with 'DOSE UNIT IS CORRECT AS RECORDED' (Site from DM).		
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 100 mg, 200 mg, etc) instead of amount in mL, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. '(Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:19:32
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'every week (QS)'	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	



US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

US3372110

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'un UNK 2010'	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:23:58
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:23:58



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:23:58

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	02 Oct 2020 19:23:58

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 19:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:27:51
Data point term sent to Coder	System	02 Oct 2020 19:26:13
User entered 'singulair'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'chronic sinusitis'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '10'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	



US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'un UNK 2010'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	02 Oct 2020 19:25:14
	(b) (4)	

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 19:25:14

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 19:25:14

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Oct 2020 19:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:29:47
Data point term sent to Coder	System	02 Oct 2020 19:29:23
User entered 'azithromycin'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:08:19
Query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' answered with 'Updated' (Site from DM).	Mary Sergalis (b) (4)	13 Nov 2020 20:26:05
User opened query 'Per CDM: Requery: Response noted, however no AE has been recorded in AE form for this indication. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:17:15
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:15:22
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'SINUS INFECTION IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:47:04
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:22
User entered 'sinus infection'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '250'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '04 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '08 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:49:53
Query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.'	Mary Sergalis (b) (4)	13 Nov 2020 20:26:25
answered with 'Updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	13 Nov 2020 20:26:17
User opened query 'Per CDM: Requery: Response noted, however as per protocol the indication is not a solicited event. Please consider to update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:45:04
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:42:36
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'SINUS INFECTION IS RECOGNIZED AS AN SOLICITED EVENT. SUBJECT DID SEEK MEDICAL TREATMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:50:51
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User entered '1'	System	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User entered '1'	System	02 Oct 2020 19:28:25

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:33
User entered '804 (804)'	System	02 Oct 2020 19:28:25

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:26:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:26:43
Data point term sent to Coder	System	02 Oct 2020 19:30:25
User entered 'methylprednisolone'	Peter Jacob (b) (4)	02 Oct 2020 19:29:59



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:56:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'ACUTE SINUSITIS IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:53:05
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:20:59
User entered 'acute sinusitis'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '4'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '04 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '10 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

US3372110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:56:50
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'ACUTE SINUSITIS IS RECOGNIZED AS AN SOLICITED EVENT. SUBJECT DID SEEK MEDICAL TREATMENT AS WELL AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:54:59
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:21:05
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User entered '1'	System	02 Oct 2020 19:29:59

**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User entered '1'	System	02 Oct 2020 19:29:59



**US3372110**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:38:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:34:37
User entered '804 (804)'	System	02 Oct 2020 19:29:59

US3372110

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:38:46**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	02 Oct 2020 19:11:16

**US3372110**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:38:46**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:17
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '15 Sep 2020'	(b) (4) Mary Sergalis (b) (4)	10 Dec 2020 16:14:11

US3372110

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:46

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:17
User closed query 'Per CDM: Please confirm if Primary Reason for Dosing Discontinuation should be marked as Due to SARS-COV-2 and reconcile if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:34:28
Query 'Per CDM: Please confirm if Primary Reason for Dosing Discontinuation should be marked as Due to SARS-COV-2 and reconcile if necessary. Thank you' answered with 'Confirmed, Subject did not receive the 2nd dose due to a positive COVID test, but will continue in the study.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:33:52
User opened query 'Per CDM: Please confirm if Primary Reason for Dosing Discontinuation should be marked as Due to SARS-COV-2 and reconcile if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 12:33:09
User signature succeeded.	Mira Baron (b) (4)	02 Apr 2021 15:36:43
Signature has been broken.	(b) (4) Mary Sergalis (b) (4)	10 Mar 2021 16:34:06
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Mar 2021 16:34:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4) Mary Sergalis (b) (4)	10 Dec 2020 16:14:11

US3372110

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:46

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:09:17
User closed query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 01:37:00
User signature succeeded.	Mira Baron (b) (4)	02 Apr 2021 15:36:43
Query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 21:19:59
User entered '#3 POSITIVE FOR COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 21:19:52
User opened query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:54:18
Signature has been broken.	Mary Sergalis (b) (4)	10 Mar 2021 16:34:06
User entered 'Positive For Covid 19' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Mar 2021 16:34:06
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered empty.	Mary Sergalis (b) (4)	10 Dec 2020 16:14:11

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:04
User entered 'US'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 20:58:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '2'	System	02 Dec 2020 03:56:12
User entered '1'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:04
User entered 'US'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 20:58:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '2'	System	02 Dec 2020 03:56:12
User entered '1'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:38:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '16/Nov/2020 21:53'	(b) (4) System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:38:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:04
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:04
User entered 'US'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 20:58:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '2'	System	02 Dec 2020 03:56:12
User entered '1'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:38:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered '02/Dec/2020 03:56'	(b) (4) System	02 Dec 2020 03:56:12

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:38:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 20:58:13
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:12

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'USA-US056-2020-MRNA-1273-P301000007'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'No (N)'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Mira'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'Baron'	System	16 Nov 2020 21:53:09



**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '2277 Palm beach Lakes Blvd'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered 'West Palm Beach'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:53:22
User entered '33409'	System	16 Nov 2020 21:53:09

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:38:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:56:04
User entered 'US'	System	16 Nov 2020 21:53:28

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 20:58:30
User signature succeeded.	Mira Baron (b) (4)	15 Feb 2021 23:05:48
	(b) (4)	
User entered '2'	System	02 Dec 2020 03:56:12
User entered '1'	System	16 Nov 2020 21:53:28

**US3372110**

**Folder: SAE USA-US056-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:38:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered '11/Mar/2021 15:58'	(b) (4) System	11 Mar 2021 20:58:30

US3372110

Folder: SAE USA-US056-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:38:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 16:30:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:58:30