

US3052291 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:56:50

All time stamps listed in this document are displayed in GMT

US3052291

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 16:46:27

Generated On: 11 Aug 2021 21:56:50

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[Participant ID](#)

US3052291

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

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US3052291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:47:17

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 16:47:11

Generated On: 11 Aug 2021 21:56:50

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 16:47:11

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 16:47:15

Generated On: 11 Aug 2021 21:56:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	APPENDIX REMOVAL
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	C-SECTION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	ALLERGY: OPIATES
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Mar 2021 16:47:12

Generated On: 11 Aug 2021 21:56:50

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:47:17

Generated On: 11 Aug 2021 21:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:10
Height (xxx.x)	163 cm
Weight (xxx.x)	56.2 kg
BMI (xxx.x)	21.15247 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:47:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

Date of assessment (dd MMM yyyy) 21 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 16:47:15

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	21 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 16:47:15

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Mar 2021 16:47:15

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 107206

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

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)	21 AUG 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 17:10
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

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)	21 AUG 2020
Time of assessment (00:00-23:59)	18:43 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 18:43
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:47:17

Generated On: 11 Aug 2021 21:56:50

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 17:54 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 17:54

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:47:18

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

17:37 (24 HR)

Collection date and time (derived)

21 AUG 2020 17:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:47:17

Generated On: 11 Aug 2021 21:56:50

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:39	21 AUG 2020 17:39
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:47:17

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:42

PC Open Date & Time

21 AUG 2020 18:14

PC Close Date & Time

21 AUG 2020 20:44

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**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

97.3 °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	21 AUG 2020 21:59
PC Open Date & Time	21 AUG 2020 21:39
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

23 AUG 2020 09:12

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

25 AUG 2020 23:30

---

PC Open Date & Time

25 AUG 2020 12:00

---

PC Close Date & Time

26 AUG 2020 11:59

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US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**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

97.5 °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

27 AUG 2020 09:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 18:42

PC Open Date & Time

21 AUG 2020 18:14

PC Close Date & Time

21 AUG 2020 20:44

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**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

21 AUG 2020 22:02

PC Open Date & Time

21 AUG 2020 21:39

PC Close Date & Time

22 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 09:13

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**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

23 AUG 2020 18:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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

24 AUG 2020 19:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**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

25 AUG 2020 23:30

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 09:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**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 ☐

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 18:42
PC Open Date & Time	21 AUG 2020 18:14
PC Close Date & Time	21 AUG 2020 20:44

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**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 ☐

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 22:02
PC Open Date & Time	21 AUG 2020 21:39
PC Close Date & Time	22 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**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 ☒

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 09:13
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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

EAB) (1725)

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US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1879

EAB) (1725)

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:31
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 1879

EAB) (1725)

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 09:26
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 ☐



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Yes ☐

PC Time stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3052291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:38

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:38

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:36

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:35

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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



US3052291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

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)	18 SEP 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3052291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	14:34 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:34
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	93 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3052291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3052291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	18 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 14:04 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 14:04

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

US3052291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

18 SEP 2020 13:30

US3052291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:35	18 SEP 2020 13:35
Nasopharyngeal Swab 2	No		

US3052291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:35

PC Open Date & Time

18 SEP 2020 14:24

PC Close Date & Time

18 SEP 2020 16:54

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	18 SEP 2020 21:34
PC Open Date & Time	18 SEP 2020 17:49
PC Close Date & Time	19 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 11:48

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 19:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 23:57

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 23:25

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 08:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:37

PC Open Date & Time

18 SEP 2020 14:24

PC Close Date & Time

18 SEP 2020 16:54

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**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

18 SEP 2020 21:31

PC Open Date & Time

18 SEP 2020 17:49

PC Close Date & Time

19 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**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

20 SEP 2020 11:48

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**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

20 SEP 2020 19:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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

21 SEP 2020 23:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**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

22 SEP 2020 20:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**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

23 SEP 2020 23:26

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 08:49

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**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 ☐

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 14:37
PC Open Date & Time	18 SEP 2020 14:24
PC Close Date & Time	18 SEP 2020 16:54

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**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 ☐

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 21:30
PC Open Date & Time	18 SEP 2020 17:49
PC Close Date & Time	19 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 11:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**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 ☒

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:56
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**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 ☒

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 23:58
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 ☒

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:37
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 ☒

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 23:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 08:50
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59



US3052291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:36

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:36

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:37

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:37

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:37

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:37

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3052291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:47:20

Generated On: 11 Aug 2021 21:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 12:00
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3052291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3052291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

12:35 (24 HR)

Collection date and time (derived)

14 OCT 2020 12:35

US3052291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:47:19

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

<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	21 OCT 2020 00:03:41
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 OCT 2020 16:17:53
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 07:30:28

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 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	18 NOV 2020 09:56:33
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 23:29:12
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59



US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

02 DEC 2020 20:09:27

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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	06 DEC 2020 18:39:05
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 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	13 DEC 2020 11:24:19
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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24 DEC 2020 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 11:25:18
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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 JAN 2021 23:57:18
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 JAN 2021 19:30:36
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59



US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

19 JAN 2021 16:10:27

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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	25 JAN 2021 15:31:38
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 14:02:13
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have 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	07 FEB 2021 11:42:09
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 FEB 2021 13:54:32
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

<b>TIMEPOINT</b>	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	21 FEB 2021 22:51:04
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

01 MAR 2021 14:38:48

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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	10 MAR 2021 08:24:31
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59



US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

14 MAR 2021 14:04:32

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

21 MAR 2021 11:41:46

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

29 MAR 2021 10:01:45

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 09:48:49
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

18 APR 2021 21:53:06

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

25 APR 2021 20:09:29

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59



US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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

02 MAY 2021 12:34:38

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JUL 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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°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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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°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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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18 NOV 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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°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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 <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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2022 23:59

US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**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 ☐

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3052291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3052291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:56:50

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 14:39:14

US3052291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:38

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3052291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:34

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:35

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:35

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:47:20

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3052291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 11:55
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:47:20

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3052291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:47:20

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 MAR 2021

Collection time (00:00-23:59)

12:43 (24 HR)

Collection date and time (derived)

10 MAR 2021 12:43



US3052291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 02:12:41

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 02:12:41

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3052291**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

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*

**US3052291**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052291

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:56:50

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"/>

**US3052291**

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

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

**Generated On: 11 Aug 2021 21:56:50**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3052291

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3052291

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 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> )	14 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

US3052291

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Height	165 cm
Weight	55 kg
BMI (xxx.x)	20.20202

US3052291

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Height	165 cm
Weight	55 kg
BMI (xxx.x)	20.20202
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)	14 JAN 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:45
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3052291

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Height	165 cm
Weight	55 kg
BMI (xxx.x)	20.20202
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)	14 JAN 2021
Time of assessment (00:00-23:59)	16:09 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 16:09
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3052291

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3052291

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

Form: Pregnancy Test

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 14 JAN 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3052291

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:46:31

Generated On: 11 Aug 2021 21:56:50

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 15:37 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 15:37

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

US3052291

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:46:32

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

15:15 (24 HR)

Collection date and time (derived)

14 JAN 2021 15:15



US3052291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 16:46:31

Generated On: 11 Aug 2021 21:56:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:19
Collection Date and Time (derived)	14 JAN 2021 15:19

US3052291

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:31

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

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

US3052291

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:46:30

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3052291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:46:30

Generated On: 11 Aug 2021 21:56:50

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	

US3052291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:46:30

Generated On: 11 Aug 2021 21:56:50

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

US3052291

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:46:30

Generated On: 11 Aug 2021 21:56:50

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.*



US3052291

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	9 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3052291

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:46:29

Generated On: 11 Aug 2021 21:56:50

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)

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?

US3052291

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:29

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

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

MISSED

If Contact Not Made, please provide Comments

US3052291

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:46:39

Generated On: 11 Aug 2021 21:56:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052291

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3052291

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

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) \_\_\_\_\_

US3052291

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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



US3052291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

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

Collection date (dd MMM yyyy)	23 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:51 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 MAR 2021 15:51
------------------------------------	-------------------

US3052291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Apr 2021 16:31:25

Generated On: 11 Aug 2021 21:56:50

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 16:46:29

Generated On: 11 Aug 2021 21:56:50

---

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

Yes ☒

No ☐

---

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

---

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Name of Medication FLONASE (FLUTICASONE)

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 TWICE A YEAR; LAST  
INJECTION AUG 2020

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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EAB) (1725)

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US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3052291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 15:43:32

Generated On: 11 Aug 2021 21:56:50

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3052291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:56:50

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3052291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:56:50

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3052291 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

**US3052291**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:56:50**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'US3052291'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:19

**US3052291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	Nicole Davis (b) (4)	21 Aug 2020 22:11:00

US3052291

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:56:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	21 Aug 2020 22:40:19
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	21 Aug 2020 22:40:19
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	21 Aug 2020 22:13:39
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:20

**US3052291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Clinic (Clinic)'	Nicole Davis (b) (4)	21 Aug 2020 22:11:00

**US3052291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'SCRN'	System	21 Aug 2020 22:11:00



**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered (b) (6) 1980'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:22

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
Query 'Per CDM please complete the form' canceled (Site from DM).	(b) (4)	09 Sep 2020 10:33:44
User entered '40'	(b) (4), (b) (6)	02 Sep 2020 17:58:49
User opened query 'Per CDM please complete the form' (Site from DM).		01 Sep 2020 09:02:10

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'YEARS'	System	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '40'	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49



**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4)	02 Sep 2020 17:58:49
	(b) (4), (b) (6)	

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

**US3052291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:50**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 17:58:49

US3052291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:56:50

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	21 Aug 2020 22:39:03
Query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	21 Aug 2020 22:39:03
User entered '21 Aug 2020' reason for change: Data Entry Error	Nicole Davis (b) (4)	21 Aug 2020 22:39:03
User opened query 'Informed Consent Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	21 Aug 2020 22:11:28
User entered '21 Jul 2020'	System	21 Aug 2020 22:11:28
	Nicole Davis (b) (4)	21 Aug 2020 22:11:28
	(b) (4)	



**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Aug 2020'	System	21 Aug 2020 22:39:03
User entered 'Jul 2020'	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2020'	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Amendment 2 (2)'	Nicole Davis (b) (4)	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4)	
	Nicole Davis (b) (4)	21 Aug 2020 22:11:28
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:20



**US3052291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:50**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'I'	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 21:56:50**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:11:10

**US3052291**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 21:56:50**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 16:55:07

US3052291

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per MM, please update event term to reflect condition (reported as appendix only) ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:03:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:38:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:38:30
Data point term sent to Coder	System	03 Feb 2021 21:38:05
Query 'Per MM, please update event term to reflect condition (reported as appendix only) ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:37:33
Coding entries removed.		03 Feb 2021 21:37:24
User entered 'APPENDIX removal' reason for change: Data Entry Error		03 Feb 2021 21:37:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Appendix disorder, LLT: Appendix disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:29:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:29:48
Data point term sent to Coder	System	14 Dec 2020 20:27:22
Query 'CDM-Coding:for coding purpose, please provide further information, related to Appendix cancer or Ruptured appendix,please update the term accordingly. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:26:41
User opened query 'Per MM, please update event term to reflect condition (reported as appendix only) ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:34:40
User opened query 'CDM-Coding:for coding purpose, please provide further information, related to Appendix cancer or Ruptured appendix,please update the term accordingly. ' (Site from System).	Coder Import (b) (4) (b) (4)	03 Nov 2020 03:34:12
Data point term sent to Coder	System	28 Oct 2020 16:56:44

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition](#)

Audit	User	Time (GMT)
User entered 'Appendix'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'UN UNK 1996'	Stacey Saldua (b) (4)	28 Oct 2020 16:56:06
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 16:56:06



**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 1996'	Stacey Saldua (b) (4)	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 1996'	System	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '1996'	System	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 1996'	System	28 Oct 2020 16:56:06

**US3052291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '1996'	System	28 Oct 2020 16:56:06

US3052291

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 11:34:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Reviewed and updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 17:49:33
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		16 Feb 2021 14:57:16
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).		04 Feb 2021 15:03:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:55:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:55:30
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:40:30
Data point term sent to Coder	System	03 Feb 2021 21:40:06

US3052291

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:56:50

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' answered with 'updated' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	03 Feb 2021 21:39:35
		03 Feb 2021 21:39:29
User entered 'CHOLEcystectomy' reason for change: Data Entry Error		03 Feb 2021 21:39:29
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).		08 Jan 2021 19:12:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Unevaluable event, LLT: Unevaluable event - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:40:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:40:41
Data point term sent to Coder	System	14 Dec 2020 20:27:23
Query 'CDM-Coding,For coding purposes, Please expand/spell out the reported abbreviation CHOLE and provide the full text. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:26:43
User opened query 'CDM-Coding,For coding purposes, Please expand/spell out the reported abbreviation CHOLE and provide the full text. ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Nov 2020 07:08:33
Data point term sent to Coder	System	28 Oct 2020 16:57:47
User entered 'Chole'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 16:57:26



**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2005'	Stacey Saldua (b) (4)	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2005'	Stacey Saldua (b) (4)	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2005'	System	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2005'	System	28 Oct 2020 16:57:26

**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2005'	System	28 Oct 2020 16:57:26



**US3052291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2005'	System	28 Oct 2020 16:57:26

US3052291

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:04:45
Data point term sent to Coder	System	28 Oct 2020 16:58:49
User entered 'C-Section'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2000'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2000'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2000'	System	28 Oct 2020 16:58:15



**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2000'	System	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2000'	System	28 Oct 2020 16:58:15

**US3052291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2000'	System	28 Oct 2020 16:58:15

US3052291

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:05:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:05:50
Data point term sent to Coder	System	28 Oct 2020 16:59:50
User entered 'C-Section'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'UN UNK 2007'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:57
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4)	28 Oct 2020 16:58:57
	Stacey Saldua (b) (4)	
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2007'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:57



**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2007'	System	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2007'	System	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2007'	System	28 Oct 2020 16:58:57

**US3052291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2007'	System	28 Oct 2020 16:58:57

US3052291

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:05:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:05:49
Data point term sent to Coder	System	28 Oct 2020 16:59:50
User entered 'C-Section'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2010'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34



**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2010'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2010'	System	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2010'	System	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2010'	System	28 Oct 2020 16:59:34

**US3052291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2010'	System	28 Oct 2020 16:59:34

US3052291

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:06:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:06:47
Data point term sent to Coder	System	28 Oct 2020 17:00:51
User entered 'C-Section'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08



**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'UN UNK 2014'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'UN UNK 2014'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:00:08

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2014'	System	28 Oct 2020 17:00:08

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2014'	System	28 Oct 2020 17:00:08

**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2014'	System	28 Oct 2020 17:00:08



**US3052291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2014'	System	28 Oct 2020 17:00:08

US3052291

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:21
Data point term sent to Coder	System	28 Oct 2020 17:01:53
User entered 'Allergy: Seasonal'	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 2015'	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2015'	System	28 Oct 2020 17:01:11



**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2015'	System	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered empty.	System	28 Oct 2020 17:01:11

**US3052291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered empty.	System	28 Oct 2020 17:01:11

US3052291

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:56:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:11
Data point term sent to Coder	System	28 Oct 2020 17:04:06
User entered 'Allergy: opiates'	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'UN UNK 1996'	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09



**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 1996'	System	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '1996'	System	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered empty.	System	28 Oct 2020 17:03:09

**US3052291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered empty.	System	28 Oct 2020 17:03:09

US3052291

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:56:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 17:52:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 17:52:07
Data point term sent to Coder	System	12 Mar 2021 17:51:26
User entered 'Gallstones'	(b) (4), (b) (6)	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:50:50



**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2005'	System	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2005'	System	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'Jan 2005'	System	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 21:56:50**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '2005'	System	12 Mar 2021 17:50:50

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55
	(b) (4)	



**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '17:10'	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '21 Aug 2020 17:10'	System	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '163' cm	(b) (4)	
	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55
DataPoint set to visible.	(b) (4)	
	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '56.2' kg	(b) (4)	
	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55
DataPoint set to visible.	(b) (4)	
	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered '21.15247'	System	28 Oct 2020 17:57:55
DataPoint set to visible.	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'kg/m2'	System	28 Oct 2020 17:57:55
DataPoint set to visible.	System	21 Aug 2020 22:11:28

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55



**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'bpm'	System	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'breaths/min'	System	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'mmHg'	System	28 Oct 2020 17:57:55



**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	Stacey Saldua (b) (4)	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered 'mmHg'	System	28 Oct 2020 17:57:55

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01

**US3052291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01

**US3052291**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4)	28 Oct 2020 17:58:47
	Stacey Saldua (b) (4)	
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	Stacey Saldua (b) (4)	28 Oct 2020 17:58:47

**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '21 Aug 2020'	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

US3052291

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:56:50

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	(b) (4)	03 Feb 2021 21:40:59
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	28 Oct 2020 17:59:30
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30
	(b) (4)	



**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

US3052291

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:56:50

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

**US3052291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:50**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:40:59
User entered '1'	Stacey Saldua (b) (4)	28 Oct 2020 17:59:30

US3052291

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query "Per CDM, re-query: Please note that pregnancy test data is recorded at Visit 1 Day 1 and per CCGs, If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at V1D1. Please also note that, per query response, subjects has an IUD in place since 2015, yet no such information is recorded on the Med History page. Kindly review and update as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 16:52:32
Query "Per CDM, re-query: Please note that pregnancy test data is recorded at Visit 1 Day 1 and per CCGs, If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at V1D1. Please also note that, per query response, subjects has an IUD in place since 2015, yet no such information is recorded on the Med History page. Kindly review and update as appropriate' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:10:28
User entered 'Yes (Y)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:10:22
User opened query "Per CDM, re-query: Please note that pregnancy test data is recorded at Visit 1 Day 1 and per CCGs, If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at V1D1. Please also note that, per query response, subjects has an IUD in place since 2015, yet no such information is recorded on the Med History page. Kindly review and update as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 15:26:50

US3052291

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM, re-query: Please note that pregnancy test data is recorded at Visit 1 Day 1 and per CCGs, If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at VID1. Please also note that, per query response, subjects has an IUD, yet no such information is recorded on the Con Med page. Kindly review and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:12:00
User opened query 'Per CDM, re-query: Please note that pregnancy test data is recorded at Visit 1 Day 1 and per CCGs, If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at VID1. Please also note that, per query response, subjects has an IUD, yet no such information is recorded on the Con Med page. Kindly review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:41:32
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:29:08
User entered 'No (N)' reason for change: Data Entry Error		03 Feb 2021 21:46:11
User entered 'Yes (Y)' reason for change: Data Entry Error		03 Feb 2021 21:45:35
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' answered with 'subject has had an IUD birth control method in place since 2015' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:41:38
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:37:38
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:00:00



**US3052291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	13 Feb 2021 23:10:22
User entered empty; reason for change Data Entry Error	amy sheets (b) (4)	03 Feb 2021 21:46:11
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:45:35
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:00:00
	(b) (4)	

**US3052291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4) amy sheets (b) (4)	13 Feb 2021 23:10:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:46:11
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 21:45:35
User entered empty.	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:00:00

US3052291

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	13 Feb 2021 23:10:22
User entered empty; reason for change Data Entry Error	amy sheets (b) (4)	13 Feb 2021 23:10:22
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 21:46:11
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:46:11
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 21:45:35
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:00:00
	(b) (4)	

US3052291

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Per CCGs, "Yes" or "No" should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:40:24
Query 'Per CDM: Per CCGs, "Yes" or "No" should be selected for "Was FSH sample collected?". Please update accordingly. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:10:33
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:10:22
User opened query 'Per CDM: Per CCGs, "Yes" or "No" should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:29:07
User entered empty.	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:00:00

**US3052291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:00:00

**US3052291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:00:00

**US3052291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User entered empty.	System	28 Oct 2020 18:00:00

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:01:40



US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:01:40



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4)	
	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
	(b) (4)	
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40
	(b) (4)	

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:50**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

**US3052291**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

**US3052291**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:50**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	(b) (4) Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:01:40



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:50

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'I'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:01:40

**US3052291**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:50**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '0'	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

**US3052291**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:45:01
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:01:40

US3052291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Please complete all the applicable pages in this visit. ' (Site from DM).	(b) (4)	04 Feb 2021 09:17:50
Query 'Per CDM: Please complete all the applicable pages in this visit. ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:41:53
User opened query 'Per CDM: Please complete all th applicable pages in this visit. ' (Site from DM).		28 Oct 2020 11:59:03
User entered 'Yes (Y)'	Nicole Davis (b) (4)	21 Aug 2020 22:07:33
	(b) (4)	

US3052291

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:56:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	(b) (4)	21 Aug 2020 22:40:19
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	21 Aug 2020 22:40:19
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	21 Aug 2020 22:13:39
User entered '21 Aug 2020'	Nicole Davis (b) (4)	21 Aug 2020 22:07:33
	(b) (4)	

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Clinic (Clinic)'	(b) (4) Nicole Davis (b) (4) (b) (4)	21 Aug 2020 22:07:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'VISIT1'	System	21 Aug 2020 22:07:33



US3052291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	(b) (4)	21 Aug 2020 22:40:19
Query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 22:40:19
User opened query 'The Randomization Date is not equal to first dose of study drug on the Exposure Form. Please review and reconcile.' (Site from System).	System	21 Aug 2020 22:13:39
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:34

US3052291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:50

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '107206'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:34

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:50**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 20:59:34

US3052291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 08:35:34
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Per query answered the yes and no questions' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	01 Dec 2020 17:05:06
User entered 'No (N)'	Stacey Saldua (b) (4) (b) (4)	01 Dec 2020 17:04:58
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:01:13

US3052291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	01 Dec 2020 17:04:58

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:50**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	01 Dec 2020 17:04:58

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:50**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	01 Dec 2020 17:04:58

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:50**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	01 Dec 2020 17:04:58



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:50**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4)	
	Stacey Saldua (b) (4)	01 Dec 2020 17:04:58
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:14:04

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

US3052291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4)	28 Oct 2020 18:04:33
	(b) (4)	

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '17:10'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '21 Aug 2020 17:10'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98.8' F	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33
	(b) (4)	

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '79'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'bpm'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '20'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'breaths/min'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '108'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

US3052291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '68'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered missing code ND - Not Done.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

US3052291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:04:33



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18:43'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '21 Aug 2020 18:43'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98.2' F	Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '69'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'bpm'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '22'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'breaths/min'	System	28 Oct 2020 18:04:33

US3052291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:04:33

US3052291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '67'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:04:33

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:40:04



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	21 Aug 2020 22:40:04

US3052291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at VID1 to avoid duplication. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:04:57
User closed query 'Was the pregnancy test performed System is No, however data has been provided below. Please correct.' (Site from System).		13 Feb 2021 23:11:01
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at VID1 to avoid duplication. Please update accordingly. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:10:41
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	System	13 Feb 2021 23:09:43
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:09:43
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' and marked as "No" at VID1 to avoid duplication. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:30:39
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:06:02

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty; reason for change Data Entry Error	(b) (4)	13 Feb 2021 23:11:01
User entered '21 Aug 2020'	amy sheets (b) (4)	28 Oct 2020 18:06:02
	Stacey Saldua (b) (4)	
	(b) (4)	

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	13 Feb 2021 23:11:01
User entered 'Urine (URINE)'	(b) (4)	
	Stacey Saldua (b) (4)	28 Oct 2020 18:06:02
	(b) (4)	

US3052291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	13 Feb 2021 23:11:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Oct 2020 18:06:14
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	28 Oct 2020 18:06:14
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Oct 2020 18:06:02
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:06:02
	(b) (4)	

US3052291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Was FSH sample collected should be answered as yes/NO .Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:05:07
Query 'Per CDM: Was FSH sample collected should be answered as yes/NO .Thanks' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:11:06
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	13 Feb 2021 23:09:43
User opened query 'Per CDM: Was FSH sample collected should be answered as yes/NO .Thanks' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 07:44:24
User entered empty.	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:06:02

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:06:02

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	13 Feb 2021 23:11:01
User entered '17:00'	(b) (4)	
	Stacey Saldua (b) (4)	28 Oct 2020 18:06:02
	(b) (4)	



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered empty.	System	28 Oct 2020 18:06:02

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:13:39

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:13:39

US3052291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:13:39

US3052291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 22:13:39

US3052291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 21AUG2020 completed in EDC.. Please complete' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:43:01
Query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 21AUG2020 completed in EDC.. Please complete' answered with 'completed' (Site from DM).		23 Feb 2021 21:51:47
User opened query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 21AUG2020 completed in EDC.. Please complete' (Site from DM).		20 Oct 2020 19:03:25
User closed query 'The Treatment Date is not equal to System the Visit Date. Please review and reconcile.' (Site from System).		21 Aug 2020 22:40:19
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 22:40:19
User closed query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	21 Aug 2020 22:40:19
User closed query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	System	21 Aug 2020 22:40:19
User entered '21 Aug 2020' reason for change: Data Entry Error	Nicole Davis (b) (4)	21 Aug 2020 22:40:19
User opened query 'Start Date is prior to ICF Date. Please verify and reconcile.' (Site from System).	System	21 Aug 2020 22:39:03
User opened query 'Start Date is prior to the Date of Randomization. Please review and provide any needed correction.' (Site from System).	System	21 Aug 2020 22:13:39
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 22:13:39
User entered '21 Jul 2020'	Nicole Davis (b) (4)	21 Aug 2020 22:13:39

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '17:54'	(b) (4) Nicole Davis (b) (4)	21 Aug 2020 22:13:39

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '21 Aug 2020 17:54'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 17:54'	System	21 Aug 2020 22:13:39



US3052291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Left Arm (LEFT ARM)'	Nicole Davis (b) (4)	21 Aug 2020 22:13:39

US3052291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'ONCE'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:07:19

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:07:19

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '17:37'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:07:19

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '21 Aug 2020 17:37'	System	28 Oct 2020 18:07:19

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '21 Aug 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:07



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stacey Saldua (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '17:39'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '21 Aug 2020 17:39'	System	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stacey Saldua (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:07

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered empty.	System	28 Oct 2020 18:08:07



**US3052291**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:14:29

**US3052291**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '1'	System	18 Sep 2020 18:14:29

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:41:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a466ff49-319d-4137-8a90-9e2bcde58836'	System	21 Aug 2020 22:42:03
User entered 'Yes (Y)'	System	21 Aug 2020 22:42:03

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:41:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a466ff49-319d-4137-8a90-9e2bcde58836'	System	21 Aug 2020 22:42:03
User entered '98.2'	System	21 Aug 2020 22:42:03

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:41:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a466ff49-319d-4137-8a90-9e2bcde58836'	System	21 Aug 2020 22:42:03
User entered 'No (N)'	System	21 Aug 2020 22:42:03

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a466ff49-319d-4137-8a90-9e2bcde58836'	System	21 Aug 2020 22:42:03
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:03

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 18:14'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 18:14'	System	21 Aug 2020 22:13:39



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 20:44'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 20:44'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T21:57:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99f6bd98-1791-4cdd-a53a-bba8c1c311f1'	System	22 Aug 2020 01:59:44
User entered 'Yes (Y)'	System	22 Aug 2020 01:59:44

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T21:59:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99f6bd98-1791-4cdd-a53a-bba8c1c311f1'	System	22 Aug 2020 01:59:44
User entered '97.3'	System	22 Aug 2020 01:59:44

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T21:59:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99f6bd98-1791-4cdd-a53a-bba8c1c311f1'	System	22 Aug 2020 01:59:44
User entered 'No (N)'	System	22 Aug 2020 01:59:44

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T21:59:40', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99f6bd98-1791-4cdd-a53a-bba8c1c311f1'	System	22 Aug 2020 01:59:44
User entered '21 Aug 2020 21:59'	System	22 Aug 2020 01:59:44

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 21:39'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 21:39'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 11:59'	System	21 Aug 2020 22:13:39



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 2'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:10:58', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45b6e99c-63a1-4689-9d0b-69a7dbd52737'	System	23 Aug 2020 13:12:57
User entered 'Yes (Y)'	System	23 Aug 2020 13:12:57

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:12:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45b6e99c-63a1-4689-9d0b-69a7dbd52737'	System	23 Aug 2020 13:12:57
User entered '98.5'	System	23 Aug 2020 13:12:57

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:12:44', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45b6e99c-63a1-4689-9d0b-69a7dbd52737'	System	23 Aug 2020 13:12:57
User entered 'No (N)'	System	23 Aug 2020 13:12:57

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:12:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45b6e99c-63a1-4689-9d0b-69a7dbd52737'	System	23 Aug 2020 13:12:57
User entered '23 Aug 2020 09:12'	System	23 Aug 2020 13:12:57

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 3'	System	21 Aug 2020 22:13:39



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '38a90e89-d35f-40ef-b1af-8eda4e705015'	System	23 Aug 2020 22:53:20
User entered 'Yes (Y)'	System	23 Aug 2020 22:53:20

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '38a90e89-d35f-40ef-b1af-8eda4e705015'	System	23 Aug 2020 22:53:20
User entered '97.9'	System	23 Aug 2020 22:53:20

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '38a90e89-d35f-40ef-b1af-8eda4e705015'	System	23 Aug 2020 22:53:20
User entered 'No (N)'	System	23 Aug 2020 22:53:20

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:16', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '38a90e89-d35f-40ef-b1af-8eda4e705015'	System	23 Aug 2020 22:53:20
User entered '23 Aug 2020 18:53'	System	23 Aug 2020 22:53:20

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 4'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f8dec8c3-35e5-4132-af6f-cb1940e7c5f2'	System	24 Aug 2020 23:40:22
User entered 'Yes (Y)'	System	24 Aug 2020 23:40:22



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:11', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f8dec8c3-35e5-4132-af6f-cb1940e7c5f2'	System	24 Aug 2020 23:40:22
User entered '97.6'	System	24 Aug 2020 23:40:22

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:16', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f8dec8c3-35e5-4132-af6f-cb1940e7c5f2'	System	24 Aug 2020 23:40:22
User entered 'No (N)'	System	24 Aug 2020 23:40:22

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:18', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f8dec8c3-35e5-4132-af6f-cb1940e7c5f2'	System	24 Aug 2020 23:40:22
User entered '24 Aug 2020 19:40'	System	24 Aug 2020 23:40:22

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 5'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6bed2f73-a9c0-45ea-aec9-060be4bfe514'	System	26 Aug 2020 03:30:43
User entered 'Yes (Y)'	System	26 Aug 2020 03:30:43

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:31', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6bed2f73-a9c0-45ea-aec9-060be4bfe514'	System	26 Aug 2020 03:30:43
User entered '96.7'	System	26 Aug 2020 03:30:43



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6bed2f73-a9c0-45ea-aec9-060be4bfe514'	System	26 Aug 2020 03:30:43
User entered 'No (N)'	System	26 Aug 2020 03:30:43

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6bed2f73-a9c0-45ea-aec9-060be4bfe514'	System	26 Aug 2020 03:30:43
User entered '25 Aug 2020 23:30'	System	26 Aug 2020 03:30:43

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 6'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:24:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c9ea8c9f-7079-497d-a1f3-81748bee0436'	System	27 Aug 2020 13:26:04
User entered 'Yes (Y)'	System	27 Aug 2020 13:26:04

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:25:55', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c9ea8c9f-7079-497d-a1f3-81748bee0436'	System	27 Aug 2020 13:26:04
User entered '97.5'	System	27 Aug 2020 13:26:04

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:25:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c9ea8c9f-7079-497d-a1f3-81748bee0436'	System	27 Aug 2020 13:26:04
User entered 'No (N)'	System	27 Aug 2020 13:26:04



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c9ea8c9f-7079-497d-a1f3-81748bee0436'	System	27 Aug 2020 13:26:04
User entered '27 Aug 2020 09:26'	System	27 Aug 2020 13:26:04

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 7'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35



US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '28 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:17', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c8c626e4-3245-4779-a27b-f454837a5399'	System	21 Aug 2020 22:42:37
User entered 'None (1)'	System	21 Aug 2020 22:42:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c8c626e4-3245-4779-a27b-f454837a5399'	System	21 Aug 2020 22:42:37
User entered 'No (N)'	System	21 Aug 2020 22:42:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c8c626e4-3245-4779-a27b-f454837a5399'	System	21 Aug 2020 22:42:37
User entered 'No (N)'	System	21 Aug 2020 22:42:37



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:31', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c8c626e4-3245-4779-a27b-f454837a5399'	System	21 Aug 2020 22:42:37
User entered 'None (1)'	System	21 Aug 2020 22:42:37

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:35', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c8c626e4-3245-4779-a27b-f454837a5399'	System	21 Aug 2020 22:42:37
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:37

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 18:14'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 18:14'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 20:44'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 20:44'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T21:59:58', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4bf5a6e7-a3ae-4afb-afa0-46404d26caf3'	System	22 Aug 2020 02:02:28
User entered 'None (1)'	System	22 Aug 2020 02:02:28

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4bf5a6e7-a3ae-4afb-afa0-46404d26caf3'	System	22 Aug 2020 02:02:28
User entered 'No (N)'	System	22 Aug 2020 02:02:28

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4bf5a6e7-a3ae-4afb-afa0-46404d26caf3'	System	22 Aug 2020 02:02:28
User entered 'No (N)'	System	22 Aug 2020 02:02:28



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:20', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4bf5a6e7-a3ae-4afb-afa0-46404d26caf3'	System	22 Aug 2020 02:02:28
User entered 'None (1)'	System	22 Aug 2020 02:02:28

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4bf5a6e7-a3ae-4afb-afa0-46404d26caf3'	System	22 Aug 2020 02:02:28
User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:28

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 21:39'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 21:39'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 2'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:12:58', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '17b6fc8f-52e9-47f8-b0f5-3a0b59f2c948'	System	23 Aug 2020 13:13:15
User entered 'None (1)'	System	23 Aug 2020 13:13:15

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '17b6fc8f-52e9-47f8-b0f5-3a0b59f2c948'	System	23 Aug 2020 13:13:15
User entered 'No (N)'	System	23 Aug 2020 13:13:15

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:02', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '17b6fc8f-52e9-47f8-b0f5-3a0b59f2c948'	System	23 Aug 2020 13:13:15
User entered 'No (N)'	System	23 Aug 2020 13:13:15



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '17b6fc8f-52e9-47f8-b0f5-3a0b59f2c948'	System	23 Aug 2020 13:13:15
User entered 'None (1)'	System	23 Aug 2020 13:13:15

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:13', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '17b6fc8f-52e9-47f8-b0f5-3a0b59f2c948'	System	23 Aug 2020 13:13:15
User entered '23 Aug 2020 09:13'	System	23 Aug 2020 13:13:15

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 3'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:23', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '79607bcb-2890-4a92-b77e-9e3d8e260e2f'	System	23 Aug 2020 22:53:37
User entered 'None (1)'	System	23 Aug 2020 22:53:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '79607bcb-2890-4a92-b77e-9e3d8e260e2f'	System	23 Aug 2020 22:53:37
User entered 'No (N)'	System	23 Aug 2020 22:53:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '79607bcb-2890-4a92-b77e-9e3d8e260e2f'	System	23 Aug 2020 22:53:37
User entered 'No (N)'	System	23 Aug 2020 22:53:37



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:31', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '79607bcb-2890-4a92-b77e-9e3d8e260e2f'	System	23 Aug 2020 22:53:37
User entered 'None (1)'	System	23 Aug 2020 22:53:37

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '79607bcb-2890-4a92-b77e-9e3d8e260e2f'	System	23 Aug 2020 22:53:37
User entered '23 Aug 2020 18:53'	System	23 Aug 2020 22:53:37

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 4'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:21', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7c9084b4-726a-4448-8866-0dfed6e70aaa'	System	24 Aug 2020 23:40:37
User entered 'None (1)'	System	24 Aug 2020 23:40:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7c9084b4-726a-4448-8866-0dfed6e70aaa'	System	24 Aug 2020 23:40:37
User entered 'No (N)'	System	24 Aug 2020 23:40:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7c9084b4-726a-4448-8866-0dfed6e70aaa'	System	24 Aug 2020 23:40:37
User entered 'No (N)'	System	24 Aug 2020 23:40:37



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:30', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7c9084b4-726a-4448-8866-0dfed6e70aaa'	System	24 Aug 2020 23:40:37
User entered 'None (1)'	System	24 Aug 2020 23:40:37

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7c9084b4-726a-4448-8866-0dfed6e70aaa'	System	24 Aug 2020 23:40:37
User entered '24 Aug 2020 19:40'	System	24 Aug 2020 23:40:37

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 5'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:42', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2606ff9d-d527-4c08-8a50-ed8ca1083845'	System	26 Aug 2020 03:30:56
User entered 'None (1)'	System	26 Aug 2020 03:30:56

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2606ff9d-d527-4c08-8a50-ed8ca1083845'	System	26 Aug 2020 03:30:56
User entered 'No (N)'	System	26 Aug 2020 03:30:56

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2606ff9d-d527-4c08-8a50-ed8ca1083845'	System	26 Aug 2020 03:30:56
User entered 'No (N)'	System	26 Aug 2020 03:30:56



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:52', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2606ff9d-d527-4c08-8a50-ed8ca1083845'	System	26 Aug 2020 03:30:56
User entered 'None (1)'	System	26 Aug 2020 03:30:56

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:55', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2606ff9d-d527-4c08-8a50-ed8ca1083845'	System	26 Aug 2020 03:30:56
User entered '25 Aug 2020 23:30'	System	26 Aug 2020 03:30:56

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 6'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'bb9b6d9c-cbb3-46e0-aa0e-62ebef0a6d1a'	System	27 Aug 2020 13:26:31
User entered 'None (1)'	System	27 Aug 2020 13:26:31

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:06', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'bb9b6d9c-cbb3-46e0-aa0e-62ebef0a6d1a'	System	27 Aug 2020 13:26:31
User entered 'No (N)'	System	27 Aug 2020 13:26:31

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'bb9b6d9c-cbb3-46e0-aa0e-62ebef0a6d1a'	System	27 Aug 2020 13:26:31
User entered 'No (N)'	System	27 Aug 2020 13:26:31



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'bb9b6d9c-cbb3-46e0-aa0e-62ebef0a6d1a'	System	27 Aug 2020 13:26:31
User entered 'None (1)'	System	27 Aug 2020 13:26:31

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'bb9b6d9c-cbb3-46e0-aa0e-62ebef0a6d1a'	System	27 Aug 2020 13:26:31
User entered '27 Aug 2020 09:26'	System	27 Aug 2020 13:26:31

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 7'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35



US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '28 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:41', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'None (0)'	System	21 Aug 2020 22:42:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered 'No (N)'	System	21 Aug 2020 22:42:55

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T18:42:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '813afd0a-7ccc-4ba7-b930-209ed54e25a6'	System	21 Aug 2020 22:42:55
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:55

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 18:14'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 18:14'	System	21 Aug 2020 22:13:39



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 20:44'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 20:44'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 22:13:39

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:30', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:40', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:42', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:44', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'None (0)'	System	22 Aug 2020 02:02:55



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:48', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered 'No (N)'	System	22 Aug 2020 02:02:55

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-21T22:02:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '85420baf-7d4f-460a-8080-eb9e54f335d0'	System	22 Aug 2020 02:02:55
User entered '21 Aug 2020 22:02'	System	22 Aug 2020 02:02:55

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Aug 2020 21:39'	System	21 Aug 2020 22:40:19
User entered '21 Jul 2020 21:39'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 2'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:40', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:42', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:48', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:50', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'None (0)'	System	23 Aug 2020 13:13:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:53', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered 'No (N)'	System	23 Aug 2020 13:13:58

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T09:13:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5114983d-3187-4408-acca-54b3ac104441'	System	23 Aug 2020 13:13:58
User entered '23 Aug 2020 09:13'	System	23 Aug 2020 13:13:58

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '22 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 3'	System	21 Aug 2020 22:13:39



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:41', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'No interference with activity (1)'	System	23 Aug 2020 22:53:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:44', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'None (0)'	System	23 Aug 2020 22:53:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'None (0)'	System	23 Aug 2020 22:53:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'None (0)'	System	23 Aug 2020 22:53:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'None (0)'	System	23 Aug 2020 22:53:59

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'None (0)'	System	23 Aug 2020 22:53:59

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered 'No (N)'	System	23 Aug 2020 22:53:59

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-23T18:53:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '0b435ca9-6006-4484-80ea-07120bfd96d3'	System	23 Aug 2020 22:53:59
User entered '23 Aug 2020 18:53'	System	23 Aug 2020 22:53:59



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '23 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 4'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'No interference with activity (1)'	System	24 Aug 2020 23:40:58

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:40', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'None (0)'	System	24 Aug 2020 23:40:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'None (0)'	System	24 Aug 2020 23:40:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'None (0)'	System	24 Aug 2020 23:40:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'None (0)'	System	24 Aug 2020 23:40:58



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'None (0)'	System	24 Aug 2020 23:40:58

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:52', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered 'No (N)'	System	24 Aug 2020 23:40:58

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-24T19:40:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86b79bb3-5169-484c-99dd-735a1e0af955'	System	24 Aug 2020 23:40:58
User entered '24 Aug 2020 19:40'	System	24 Aug 2020 23:40:58

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '24 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 5'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:30:58', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:02', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:10', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'None (0)'	System	26 Aug 2020 03:31:19

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered 'No (N)'	System	26 Aug 2020 03:31:19

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-25T23:31:15', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '09348bc6-e1f7-4965-9f24-9b623130c10a'	System	26 Aug 2020 03:31:19
User entered '25 Aug 2020 23:31'	System	26 Aug 2020 03:31:19

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '25 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 11:59'	System	21 Aug 2020 22:13:39



US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 6'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:34', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'None (0)'	System	27 Aug 2020 13:27:00

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:53', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered 'No (N)'	System	27 Aug 2020 13:27:00



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-08-27T09:26:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '37eea3c7-b17c-45c1-9268-18aeb1be21e3'	System	27 Aug 2020 13:27:00
User entered '27 Aug 2020 09:26'	System	27 Aug 2020 13:27:00

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '26 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 7'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35



**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

US3052291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 22:40:19
User entered '27 Jul 2020 12:00'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 22:40:19
User entered '28 Jul 2020 11:59'	System	21 Aug 2020 22:13:39

**US3052291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:46

US3052291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 04:33:49
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed call performed 9/1/2020' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 21:53:11
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Oct 2020 18:08:46
User entered '1 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:08:46



**US3052291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:46

**US3052291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:08:46
	(b) (4)	

**US3052291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:14:40

**US3052291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'I'	System	18 Sep 2020 18:14:40

**US3052291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:09:27

US3052291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 04:34:17
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed call performed 9/8/2020' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 21:53:37
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Oct 2020 18:09:27
User entered '8 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:09:27

**US3052291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:09:27

**US3052291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:09:27
	(b) (4)	



**US3052291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:14:48

**US3052291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '1'	System	18 Sep 2020 18:14:48

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:58:27

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:58:27

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:58:27

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:58:27

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:14:56

**US3052291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'I'	System	18 Sep 2020 18:14:56



US3052291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:56:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:44:56
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'entered in edc' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:44:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:51:23
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	18 Sep 2020 18:15:15

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:15:15

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:15:15

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'VISIT2'	System	18 Sep 2020 18:15:15

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4)	28 Oct 2020 18:16:25
	(b) (4)	

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

US3052291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Please review source document and verify the time. Thank you.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 04 Feb 2021 11:51:02
Query 'Per CDM: Please review source document and verify the time. Thank you.' answered with 'updated' (Site from DM).		03 Feb 2021 21:48:43
User entered '13:15' reason for change: Data Entry Error		03 Feb 2021 21:48:35
User opened query 'Per CDM: Please review source document and verify the time. Thank you.' (Site from DM).		09 Dec 2020 16:20:59
User entered '01:15'	Stacey Saldua (b) (4)	28 Oct 2020 18:16:25
	(b) (4)	



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '18 Sep 2020 13:15'	System	03 Feb 2021 21:48:35
User entered '18 Sep 2020 01:15'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98.4' F	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '74'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'bpm'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'breaths/min'	System	28 Oct 2020 18:16:25



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '96'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '61'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14:34'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '18 Sep 2020 14:34'	System	28 Oct 2020 18:16:25

US3052291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98.6' F	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Oral (Oral)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '77'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'bpm'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'breaths/min'	System	28 Oct 2020 18:16:25



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '93'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '64'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:25

US3052291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	28 Oct 2020 18:16:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:15:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:15:25

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:56

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4)	
	Stacey Saldua (b) (4)	28 Oct 2020 18:16:56
	(b) (4)	



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Urine (URINE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:56

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Negative (NEGATIVE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:56

US3052291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Please not that the "Was FSH sample collected " question is to be answered with "Yes" or "No" and not left empty as per the CCGs. Only if "Yes" is selected, the date and time of FSH collection is to be recorded in the fields below. Please update accordingly.' (Site from DM). Query 'Per CDM: Please not that the "Was FSH sample collected " question is to be answered with "Yes" or "No" and not left empty as per the CCGs. Only if "Yes" is selected, the date and time of FSH collection is to be recorded in the fields below. Please update accordingly.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:24:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 21:49:29
User opened query 'Per CDM: Please not that the "Was FSH sample collected " question is to be answered with "Yes" or "No" and not left empty as per the CCGs. Only if "Yes" is selected, the date and time of FSH collection is to be recorded in the fields below. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 05:43:17
User entered empty.	Stacey Saldua (b) (4)	28 Oct 2020 18:16:56
	(b) (4)	

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:16:56

US3052291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per CDM: Was FSH sample collected? = No, yet time of FSH collection is recorded. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 05:39:57
Query 'Per CDM: Was FSH sample collected? = No, yet time of FSH collection is recorded. Please review and update accordingly. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	13 Feb 2021 22:59:18
User entered empty; reason for change Data Entry Error	amy sheets (b) (4) (b) (4)	13 Feb 2021 22:59:11
User opened query 'Per CDM: Was FSH sample collected? = No, yet time of FSH collection is recorded. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:25:02
User entered '13:41'	Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:16:56

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered empty.	System	28 Oct 2020 18:16:56

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:16:19

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:16:19



US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	Stacey Saldua (b) (4)	18 Sep 2020 18:16:19

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 18:16:19

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User closed query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 18SEP2020 completed in EDC.. Please complete' (Site from DM).	(b) (4)	08 Feb 2021 16:39:55
Query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 18SEP2020 completed in EDC.. Please complete' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:49:53
User opened query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 18SEP2020 completed in EDC.. Please complete' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:04:05
User entered '18 Sep 2020'	Stacey Saldua (b) (4)	18 Sep 2020 18:16:19
	(b) (4)	

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14:04'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:16:19

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '18 Sep 2020 14:04'	System	18 Sep 2020 18:16:19

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:16:19

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'ONCE'	System	18 Sep 2020 18:16:19

US3052291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 18:16:19



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:21

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:21

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '13:30'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:21

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '18 Sep 2020 13:30'	System	28 Oct 2020 18:17:21

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '18 Sep 2020'	Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '13:35'	(b) (4) Stacey Saldua (b) (4) (b) (4)	28 Oct 2020 18:17:47



**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '18 Sep 2020 13:35'	System	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'No (N)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered empty.	System	28 Oct 2020 18:17:47

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	18 Sep 2020 18:16:26

**US3052291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '1'	System	18 Sep 2020 18:16:26

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:35:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49f47fd2-6b88-4fe9-91b0-48f1392980f1'	System	18 Sep 2020 18:35:40
User entered 'Yes (Y)'	System	18 Sep 2020 18:35:40

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:35:30', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49f47fd2-6b88-4fe9-91b0-48f1392980f1'	System	18 Sep 2020 18:35:40
User entered '98.6'	System	18 Sep 2020 18:35:40

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:35:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49f47fd2-6b88-4fe9-91b0-48f1392980f1'	System	18 Sep 2020 18:35:40
User entered 'No (N)'	System	18 Sep 2020 18:35:40

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:35:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49f47fd2-6b88-4fe9-91b0-48f1392980f1'	System	18 Sep 2020 18:35:40
User entered '18 Sep 2020 14:35'	System	18 Sep 2020 18:35:40

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 14:24'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 16:54'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:33:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f1875979-b09a-46ca-943b-1929a3151c48'	System	19 Sep 2020 01:35:02
User entered 'Yes (Y)'	System	19 Sep 2020 01:35:02



US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:34:50', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f1875979-b09a-46ca-943b-1929a3151c48'	System	19 Sep 2020 01:35:02
User entered '97.1'	System	19 Sep 2020 01:35:02

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:34:53', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f1875979-b09a-46ca-943b-1929a3151c48'	System	19 Sep 2020 01:35:02
User entered 'No (N)'	System	19 Sep 2020 01:35:02

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:34:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f1875979-b09a-46ca-943b-1929a3151c48'	System	19 Sep 2020 01:35:02
User entered '18 Sep 2020 21:34'	System	19 Sep 2020 01:35:02

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 17:49'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 2'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86748a71-3412-4a55-b1cc-f88ef12eaad5'	System	20 Sep 2020 15:48:38
User entered 'Yes (Y)'	System	20 Sep 2020 15:48:38

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:30', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86748a71-3412-4a55-b1cc-f88ef12eaad5'	System	20 Sep 2020 15:48:38
User entered '97.7'	System	20 Sep 2020 15:48:38



US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86748a71-3412-4a55-b1cc-f88ef12eaad5'	System	20 Sep 2020 15:48:38
User entered 'No (N)'	System	20 Sep 2020 15:48:38

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:35', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '86748a71-3412-4a55-b1cc-f88ef12eaad5'	System	20 Sep 2020 15:48:38
User entered '20 Sep 2020 11:48'	System	20 Sep 2020 15:48:38

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 3'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a0b2ea57-4c7c-4b06-b8a0-40f6e218515b'	System	20 Sep 2020 23:54:38
User entered 'Yes (Y)'	System	20 Sep 2020 23:54:38

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:31', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a0b2ea57-4c7c-4b06-b8a0-40f6e218515b'	System	20 Sep 2020 23:54:38
User entered '97.6'	System	20 Sep 2020 23:54:38

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a0b2ea57-4c7c-4b06-b8a0-40f6e218515b'	System	20 Sep 2020 23:54:38
User entered 'No (N)'	System	20 Sep 2020 23:54:38



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:35', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a0b2ea57-4c7c-4b06-b8a0-40f6e218515b'	System	20 Sep 2020 23:54:38
User entered '20 Sep 2020 19:54'	System	20 Sep 2020 23:54:38

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 4'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:57:48', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a87e101f-871c-4bc3-9c6c-77d8ae7e1057'	System	22 Sep 2020 03:58:00
User entered 'Yes (Y)'	System	22 Sep 2020 03:58:00

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:57:52', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a87e101f-871c-4bc3-9c6c-77d8ae7e1057'	System	22 Sep 2020 03:58:00
User entered '96.5'	System	22 Sep 2020 03:58:00

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:57:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a87e101f-871c-4bc3-9c6c-77d8ae7e1057'	System	22 Sep 2020 03:58:00
User entered 'No (N)'	System	22 Sep 2020 03:58:00

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:57:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a87e101f-871c-4bc3-9c6c-77d8ae7e1057'	System	22 Sep 2020 03:58:00
User entered '21 Sep 2020 23:57'	System	22 Sep 2020 03:58:00



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 5'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '311856af-b843-4084-b6a8-59ea29c55c8f'	System	23 Sep 2020 00:36:30
User entered 'Yes (Y)'	System	23 Sep 2020 00:36:30

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '311856af-b843-4084-b6a8-59ea29c55c8f'	System	23 Sep 2020 00:36:30
User entered '97.5'	System	23 Sep 2020 00:36:30

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:23', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '311856af-b843-4084-b6a8-59ea29c55c8f'	System	23 Sep 2020 00:36:30
User entered 'No (N)'	System	23 Sep 2020 00:36:30

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '311856af-b843-4084-b6a8-59ea29c55c8f'	System	23 Sep 2020 00:36:30
User entered '22 Sep 2020 20:36'	System	23 Sep 2020 00:36:30

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:16:19



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 6'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c457cacf-736a-45a5-a213-2205adb5f3e4'	System	24 Sep 2020 03:25:56
User entered 'Yes (Y)'	System	24 Sep 2020 03:25:56

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c457cacf-736a-45a5-a213-2205adb5f3e4'	System	24 Sep 2020 03:25:56
User entered '96.8'	System	24 Sep 2020 03:25:56

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c457cacf-736a-45a5-a213-2205adb5f3e4'	System	24 Sep 2020 03:25:56
User entered 'No (N)'	System	24 Sep 2020 03:25:56

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c457cacf-736a-45a5-a213-2205adb5f3e4'	System	24 Sep 2020 03:25:56
User entered '23 Sep 2020 23:25'	System	24 Sep 2020 03:25:56

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 7'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '26220d93-99d2-4089-84c5-cddb871eae77'	System	25 Sep 2020 12:49:41
User entered 'Yes (Y)'	System	25 Sep 2020 12:49:41

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '26220d93-99d2-4089-84c5-cddb871eae77'	System	25 Sep 2020 12:49:41
User entered '97.6'	System	25 Sep 2020 12:49:41

US3052291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:35', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '26220d93-99d2-4089-84c5-cddb871eae77'	System	25 Sep 2020 12:49:41
User entered 'No (N)'	System	25 Sep 2020 12:49:41

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:37', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '26220d93-99d2-4089-84c5-cddb871eae77'	System	25 Sep 2020 12:49:41
User entered '25 Sep 2020 08:49'	System	25 Sep 2020 12:49:41

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:36:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45159580-2cef-4c1d-9ba3-335651edee05'	System	18 Sep 2020 18:37:09
User entered 'None (1)'	System	18 Sep 2020 18:37:09

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:36:52', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45159580-2cef-4c1d-9ba3-335651edee05'	System	18 Sep 2020 18:37:09
User entered 'No (N)'	System	18 Sep 2020 18:37:09

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:36:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45159580-2cef-4c1d-9ba3-335651edee05'	System	18 Sep 2020 18:37:09
User entered 'No (N)'	System	18 Sep 2020 18:37:09

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45159580-2cef-4c1d-9ba3-335651edee05'	System	18 Sep 2020 18:37:09
User entered 'None (1)'	System	18 Sep 2020 18:37:09

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '45159580-2cef-4c1d-9ba3-335651edee05'	System	18 Sep 2020 18:37:09
User entered '18 Sep 2020 14:37'	System	18 Sep 2020 18:37:09

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 14:24'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 16:54'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:46', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f3b294de-232a-4275-a4da-30365e37ce95'	System	19 Sep 2020 01:31:08
User entered 'None (1)'	System	19 Sep 2020 01:31:08

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:50', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f3b294de-232a-4275-a4da-30365e37ce95'	System	19 Sep 2020 01:31:08
User entered 'No (N)'	System	19 Sep 2020 01:31:08

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f3b294de-232a-4275-a4da-30365e37ce95'	System	19 Sep 2020 01:31:08
User entered 'No (N)'	System	19 Sep 2020 01:31:08

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:31:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f3b294de-232a-4275-a4da-30365e37ce95'	System	19 Sep 2020 01:31:08
User entered 'None (1)'	System	19 Sep 2020 01:31:08

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:31:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f3b294de-232a-4275-a4da-30365e37ce95'	System	19 Sep 2020 01:31:08
User entered '18 Sep 2020 21:31'	System	19 Sep 2020 01:31:08

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 17:49'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 2'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e03a68af-93b9-4413-80a1-afcc2510a75b'	System	20 Sep 2020 15:48:59
User entered 'None (1)'	System	20 Sep 2020 15:48:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e03a68af-93b9-4413-80a1-afcc2510a75b'	System	20 Sep 2020 15:48:59
User entered 'No (N)'	System	20 Sep 2020 15:48:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e03a68af-93b9-4413-80a1-afcc2510a75b'	System	20 Sep 2020 15:48:59
User entered 'No (N)'	System	20 Sep 2020 15:48:59

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:55', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e03a68af-93b9-4413-80a1-afcc2510a75b'	System	20 Sep 2020 15:48:59
User entered 'None (1)'	System	20 Sep 2020 15:48:59

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:48:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e03a68af-93b9-4413-80a1-afcc2510a75b'	System	20 Sep 2020 15:48:59
User entered '20 Sep 2020 11:48'	System	20 Sep 2020 15:48:59

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 3'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:51', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52af70e7-3d3c-47f4-ba3a-c755c8709254'	System	20 Sep 2020 23:55:05
User entered 'None (1)'	System	20 Sep 2020 23:55:05

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:53', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52af70e7-3d3c-47f4-ba3a-c755c8709254'	System	20 Sep 2020 23:55:05
User entered 'No (N)'	System	20 Sep 2020 23:55:05

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:55', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52af70e7-3d3c-47f4-ba3a-c755c8709254'	System	20 Sep 2020 23:55:05
User entered 'No (N)'	System	20 Sep 2020 23:55:05

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:54:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52af70e7-3d3c-47f4-ba3a-c755c8709254'	System	20 Sep 2020 23:55:05
User entered 'None (1)'	System	20 Sep 2020 23:55:05

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:55:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52af70e7-3d3c-47f4-ba3a-c755c8709254'	System	20 Sep 2020 23:55:05
User entered '20 Sep 2020 19:55'	System	20 Sep 2020 23:55:05

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 4'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49872970-b7cc-4408-b4fc-2b2afa06bf41'	System	22 Sep 2020 03:58:15
User entered 'None (1)'	System	22 Sep 2020 03:58:15

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49872970-b7cc-4408-b4fc-2b2afa06bf41'	System	22 Sep 2020 03:58:15
User entered 'No (N)'	System	22 Sep 2020 03:58:15

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49872970-b7cc-4408-b4fc-2b2afa06bf41'	System	22 Sep 2020 03:58:15
User entered 'No (N)'	System	22 Sep 2020 03:58:15

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49872970-b7cc-4408-b4fc-2b2afa06bf41'	System	22 Sep 2020 03:58:15
User entered 'None (1)'	System	22 Sep 2020 03:58:15

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:11', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '49872970-b7cc-4408-b4fc-2b2afa06bf41'	System	22 Sep 2020 03:58:15
User entered '21 Sep 2020 23:58'	System	22 Sep 2020 03:58:15

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 5'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '64297fb9-bdf7-403c-be71-d7b026a14bc2'	System	23 Sep 2020 00:36:49
User entered 'None (1)'	System	23 Sep 2020 00:36:49

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:34', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '64297fb9-bdf7-403c-be71-d7b026a14bc2'	System	23 Sep 2020 00:36:49
User entered 'No (N)'	System	23 Sep 2020 00:36:49

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '64297fb9-bdf7-403c-be71-d7b026a14bc2'	System	23 Sep 2020 00:36:49
User entered 'No (N)'	System	23 Sep 2020 00:36:49

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '64297fb9-bdf7-403c-be71-d7b026a14bc2'	System	23 Sep 2020 00:36:49
User entered 'None (1)'	System	23 Sep 2020 00:36:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:46', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '64297fb9-bdf7-403c-be71-d7b026a14bc2'	System	23 Sep 2020 00:36:49
User entered '22 Sep 2020 20:36'	System	23 Sep 2020 00:36:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 6'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1b3933b3-3b3e-47bd-ab2e-4b910e383ac6'	System	24 Sep 2020 03:26:11
User entered 'None (1)'	System	24 Sep 2020 03:26:11

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:25:58', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1b3933b3-3b3e-47bd-ab2e-4b910e383ac6'	System	24 Sep 2020 03:26:11
User entered 'No (N)'	System	24 Sep 2020 03:26:11

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1b3933b3-3b3e-47bd-ab2e-4b910e383ac6'	System	24 Sep 2020 03:26:11
User entered 'No (N)'	System	24 Sep 2020 03:26:11

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1b3933b3-3b3e-47bd-ab2e-4b910e383ac6'	System	24 Sep 2020 03:26:11
User entered 'None (1)'	System	24 Sep 2020 03:26:11

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1b3933b3-3b3e-47bd-ab2e-4b910e383ac6'	System	24 Sep 2020 03:26:11
User entered '23 Sep 2020 23:26'	System	24 Sep 2020 03:26:11

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 7'	System	18 Sep 2020 18:16:19



US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:41', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52f089bd-70a4-4d48-8ce2-31cc38de9b0d'	System	25 Sep 2020 12:49:53
User entered 'None (1)'	System	25 Sep 2020 12:49:53

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52f089bd-70a4-4d48-8ce2-31cc38de9b0d'	System	25 Sep 2020 12:49:53
User entered 'No (N)'	System	25 Sep 2020 12:49:53

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:44', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52f089bd-70a4-4d48-8ce2-31cc38de9b0d'	System	25 Sep 2020 12:49:53
User entered 'No (N)'	System	25 Sep 2020 12:49:53

US3052291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:48', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52f089bd-70a4-4d48-8ce2-31cc38de9b0d'	System	25 Sep 2020 12:49:53
User entered 'None (1)'	System	25 Sep 2020 12:49:53

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:50', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '52f089bd-70a4-4d48-8ce2-31cc38de9b0d'	System	25 Sep 2020 12:49:53
User entered '25 Sep 2020 08:49'	System	25 Sep 2020 12:49:53

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:16:19



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:14', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:16', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:23', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'None (0)'	System	18 Sep 2020 18:37:33

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered 'No (N)'	System	18 Sep 2020 18:37:33

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T14:37:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6ac606a9-77c5-48d2-9918-31cf16408a7e'	System	18 Sep 2020 18:37:33
User entered '18 Sep 2020 14:37'	System	18 Sep 2020 18:37:33



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 14:24'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 16:54'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'None (0)'	System	19 Sep 2020 01:30:39

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'None (0)'	System	19 Sep 2020 01:30:39

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:06', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'None (0)'	System	19 Sep 2020 01:30:39

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d' User entered 'None (0)'	System	19 Sep 2020 01:30:39
	System	19 Sep 2020 01:30:39

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:14', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'None (0)'	System	19 Sep 2020 01:30:39



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:17', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'None (0)'	System	19 Sep 2020 01:30:39

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:23', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered 'No (N)'	System	19 Sep 2020 01:30:39

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-18T21:30:37', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '58d2b61b-b519-4691-ad37-b09fde99dd1d'	System	19 Sep 2020 01:30:39
User entered '18 Sep 2020 21:30'	System	19 Sep 2020 01:30:39

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '18 Sep 2020 17:49'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 2'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:10', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'None (0)'	System	20 Sep 2020 15:49:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:14', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered 'No (N)'	System	20 Sep 2020 15:49:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T11:49:15', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '7ca12572-f32f-4b5a-b6b6-802b88808d56'	System	20 Sep 2020 15:49:18
User entered '20 Sep 2020 11:49'	System	20 Sep 2020 15:49:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:16:19



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 3'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:02', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:10', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'None (0)'	System	20 Sep 2020 23:56:18

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered 'No (N)'	System	20 Sep 2020 23:56:18



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-20T19:56:14', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3eed1275-5989-4b46-8186-98b22d9ff1ef'	System	20 Sep 2020 23:56:18
User entered '20 Sep 2020 19:56'	System	20 Sep 2020 23:56:18

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 4'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:15', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:17', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:19', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:21', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:22', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'None (0)'	System	22 Sep 2020 03:58:34

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered 'No (N)'	System	22 Sep 2020 03:58:34

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-21T23:58:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '487b01c3-8d2d-4125-ab31-b9ede13d82eb'	System	22 Sep 2020 03:58:34
User entered '21 Sep 2020 23:58'	System	22 Sep 2020 03:58:34

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 5'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:36:49', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'None (0)'	System	23 Sep 2020 00:37:16

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:11', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered 'No (N)'	System	23 Sep 2020 00:37:16

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-22T20:37:13', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3b69b147-6b65-40f1-ac36-397b561dcbf5'	System	23 Sep 2020 00:37:16
User entered '22 Sep 2020 20:37'	System	23 Sep 2020 00:37:16

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:16:19



**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 6'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:11', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'None (0)'	System	24 Sep 2020 03:26:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:26', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:26:49

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:28', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'None (0)'	System	24 Sep 2020 03:26:49

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'No interference with activity (1)'	System	24 Sep 2020 03:26:49

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'None (0)'	System	24 Sep 2020 03:26:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:40', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'None (0)'	System	24 Sep 2020 03:26:49



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:42', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered 'No (N)'	System	24 Sep 2020 03:26:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-23T23:26:45', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '41d5b561-f02f-467c-8ff3-52c019030aa7'	System	24 Sep 2020 03:26:49
User entered '23 Sep 2020 23:26'	System	24 Sep 2020 03:26:49

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	18 Sep 2020 18:16:19
User entered 'Day 7'	System	18 Sep 2020 18:16:19

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:54', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:55', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:57', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10



US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:49:59', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:50:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:50:02', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'None (0)'	System	25 Sep 2020 12:50:10

US3052291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:50:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered 'No (N)'	System	25 Sep 2020 12:50:10

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-09-25T08:50:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'a94dd4d9-5557-4396-8cf0-2eae0671ad60'	System	25 Sep 2020 12:50:10
User entered '25 Sep 2020 08:50'	System	25 Sep 2020 12:50:10

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:16:19

**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:19:41



**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '25 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:19:41

**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:19:41

**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:19:41
	(b) (4)	

**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:33:41

**US3052291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'I'	System	14 Oct 2020 19:33:41

**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:06

**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '2 Oct 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:06

**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:06



**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:06
	(b) (4)	

**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:33:47

**US3052291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'I'	System	14 Oct 2020 19:33:47

**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:28

**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '9 Oct 2020'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:28

**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:28

**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) Stacey Saldua (b) (4)	28 Oct 2020 18:20:28
	(b) (4)	

**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:33:52



**US3052291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '1'	System	14 Oct 2020 19:33:52

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:02

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:02

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Clinic (Clinic)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:02

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'VISIT3'	System	14 Oct 2020 19:34:02

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '12:00'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36



**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '14 Oct 2020 12:00'	System	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '98.6' F	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered empty.	(b) (4) Avia McClain-Stocker	14 Oct 2020 19:34:36
	(b) (4)	

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '82'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'bpm'	System	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '12'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'breaths/min'	System	14 Oct 2020 19:34:36



**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '104'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '67'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'mmHg'	System	14 Oct 2020 19:34:36

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:08

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:08



**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:25

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '14 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:25

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '12:35'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:25

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '14 Oct 2020 12:35'	System	14 Oct 2020 19:35:25

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:03:28

**US3052291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered '1'	System	11 Nov 2020 18:03:28

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 64'	System	21 Aug 2020 22:13:39

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

[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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-21T00:03:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e23a396b-f540-4876-b433-df88e904199b'	System	21 Oct 2020 04:03:46
User entered 'No (N)'	System	21 Oct 2020 04:03:46



US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

Have you been exposed to someone with 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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-21T00:03:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e23a396b-f540-4876-b433-df88e904199b'	System	21 Oct 2020 04:03:46
User entered 'No (N)'	System	21 Oct 2020 04:03:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-21T00:03:41', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e23a396b-f540-4876-b433-df88e904199b'	System	21 Oct 2020 04:03:46
User entered '21 Oct 2020 00:03:41'	System	21 Oct 2020 04:03:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '20 Sep 2020 00:01'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '24 Sep 2020 23:59'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 71'	System	21 Aug 2020 22:13:39

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

[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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-29T16:17:44', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '547b6fb1-8c5d-40fd-bb1c-e2c92dfc75e3'	System	29 Oct 2020 20:18:00
User entered 'No (N)'	System	29 Oct 2020 20:18:00

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

Have you been exposed to someone with 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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-29T16:17:47', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '547b6fb1-8c5d-40fd-bb1c-e2c92dfc75e3'	System	29 Oct 2020 20:18:00
User entered 'No (N)'	System	29 Oct 2020 20:18:00

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-10-29T16:17:53', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '547b6fb1-8c5d-40fd-bb1c-e2c92dfc75e3'	System	29 Oct 2020 20:18:00
User entered '29 Oct 2020 16:17:53'	System	29 Oct 2020 20:18:00



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '27 Sep 2020 00:01'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '01 Oct 2020 23:59'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 78'	System	21 Aug 2020 22:13:39

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

[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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-04T07:30:22', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3efba468-6368-4e23-9b26-67a1942239b0'	System	04 Nov 2020 12:30:38
User entered 'No (N)'	System	04 Nov 2020 12:30:38

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

Have you been exposed to someone with 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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-04T07:30:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3efba468-6368-4e23-9b26-67a1942239b0'	System	04 Nov 2020 12:30:38
User entered 'No (N)'	System	04 Nov 2020 12:30:38

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-04T07:30:28', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '3efba468-6368-4e23-9b26-67a1942239b0'	System	04 Nov 2020 12:30:38
User entered '04 Nov 2020 07:30:28'	System	04 Nov 2020 12:30:38

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '04 Oct 2020 00:01'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '08 Oct 2020 23:59'	System	21 Aug 2020 22:13:39



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:13:39
User entered 'Day 92'	System	21 Aug 2020 22:13:39

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-18T09:56:25', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1ec41561-6f3a-48c7-97f1-764365475c88'	System	18 Nov 2020 14:56:37
User entered 'No (N)'	System	18 Nov 2020 14:56:37

US3052291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:50

Have you been exposed to someone with 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 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-18T09:56:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1ec41561-6f3a-48c7-97f1-764365475c88'	System	18 Nov 2020 14:56:37
User entered 'No (N)'	System	18 Nov 2020 14:56:37

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-18T09:56:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '1ec41561-6f3a-48c7-97f1-764365475c88'	System	18 Nov 2020 14:56:37
User entered '18 Nov 2020 09:56:33'	System	18 Nov 2020 14:56:37

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '18 Oct 2020 00:01'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:22:35
Data entry locked.	System	21 Aug 2020 22:40:19
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 22:40:19
Data entry unlocked.	System	21 Aug 2020 22:40:19
Data entry locked.	System	21 Aug 2020 22:13:39
User entered '22 Oct 2020 23:59'	System	21 Aug 2020 22:13:39

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2020-11-22T23:29:07', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd883241b-f0c2-4e22-a4d7-b2a8b3accecf3'	System	23 Nov 2020 04:29:17
User entered 'No (N)'	System	23 Nov 2020 04:29:17



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2020-11-22T23:29:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd883241b-f0c2-4e22-a4d7-b2a8b3accecf3'	System	23 Nov 2020 04:29:17
User entered 'No (N)'	System	23 Nov 2020 04:29:17

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-11-22T23:29:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd883241b-f0c2-4e22-a4d7-b2a8b3acce3'	System	23 Nov 2020 04:29:17
User entered '22 Nov 2020 23:29:12'	System	23 Nov 2020 04:29:17

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2020-12-02T20:09:13', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd39e0400-f2a9-4af5-8440-20ddbd7cb68f'	System	03 Dec 2020 01:09:33
User entered 'No (N)'	System	03 Dec 2020 01:09:33

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2020-12-02T20:09:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd39e0400-f2a9-4af5-8440-20ddbd7cb68f'	System	03 Dec 2020 01:09:33
User entered 'No (N)'	System	03 Dec 2020 01:09:33

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-12-02T20:09:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd39e0400-f2a9-4af5-8440-20ddb7cb68f'	System	03 Dec 2020 01:09:33
User entered '02 Dec 2020 20:09:27'	System	03 Dec 2020 01:09:33



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

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**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2020-12-06T18:38:41', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '21966e2b-12b2-4a0c-b2cb-a7ad0115f89d'	System	06 Dec 2020 23:39:08
User entered 'No (N)'	System	06 Dec 2020 23:39:08

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2020-12-06T18:39:03', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '21966e2b-12b2-4a0c-b2cb-a7ad0115f89d'	System	06 Dec 2020 23:39:08
User entered 'No (N)'	System	06 Dec 2020 23:39:08

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-12-06T18:39:05', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '21966e2b-12b2-4a0c-b2cb-a7ad0115f89d'	System	06 Dec 2020 23:39:08
User entered '06 Dec 2020 18:39:05'	System	06 Dec 2020 23:39:08

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2020-12-13T11:22:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f4cbc21a-43a2-4194-9588-a8943b3167ec'	System	13 Dec 2020 16:24:31
User entered 'No (N)'	System	13 Dec 2020 16:24:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2020-12-13T11:24:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f4cbc21a-43a2-4194-9588-a8943b3167ec'	System	13 Dec 2020 16:24:31
User entered 'Yes (Y)'	System	13 Dec 2020 16:24:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-12-13T11:24:10', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f4cbc21a-43a2-4194-9588-a8943b3167ec'	System	13 Dec 2020 16:24:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 16:24:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-12-13T11:24:19', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'f4cbc21a-43a2-4194-9588-a8943b3167ec' User entered '13 Dec 2020 11:24:19'	System	13 Dec 2020 16:24:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2020-12-27T11:25:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '18a5e5ac-4f92-4c1d-9ba8-87a099a4abe2'	System	27 Dec 2020 16:25:21
User entered 'No (N)'	System	27 Dec 2020 16:25:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2020-12-27T11:25:15', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '18a5e5ac-4f92-4c1d-9ba8-87a099a4abe2'	System	27 Dec 2020 16:25:21
User entered 'No (N)'	System	27 Dec 2020 16:25:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2020-12-27T11:25:18', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '18a5e5ac-4f92-4c1d-9ba8-87a099a4abe2' User entered '27 Dec 2020 11:25:18'	System	27 Dec 2020 16:25:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-06T23:57:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd57d8f01-01ee-4bab-87a0-6c99b9d96ff5'	System	07 Jan 2021 04:57:21
User entered 'No (N)'	System	07 Jan 2021 04:57:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-01-06T23:57:15', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd57d8f01-01ee-4bab-87a0-6c99b9d96ff5'	System	07 Jan 2021 04:57:21
User entered 'No (N)'	System	07 Jan 2021 04:57:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-01-06T23:57:18', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'd57d8f01-01ee-4bab-87a0-6c99b9d96ff5'	System	07 Jan 2021 04:57:21
User entered '06 Jan 2021 23:57:18'	System	07 Jan 2021 04:57:21

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-12T19:30:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '61500532-2b5c-4ca5-8dab-916fd1d756df'	System	13 Jan 2021 00:30:40
User entered 'Yes (Y)'	System	13 Jan 2021 00:30:40



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-01-12T19:30:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '61500532-2b5c-4ca5-8dab-916fd1d756df'	System	13 Jan 2021 00:30:40
User entered 'No (N)'	System	13 Jan 2021 00:30:40

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-12T19:30:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '61500532-2b5c-4ca5-8dab-916fd1d756df'	System	13 Jan 2021 00:30:40
User entered 'No (N)'	System	13 Jan 2021 00:30:40

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-12T19:30:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '61500532-2b5c-4ca5-8dab-916fd1d756df'	System	13 Jan 2021 00:30:40
User entered 'No (N)'	System	13 Jan 2021 00:30:40

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-01-12T19:30:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '61500532-2b5c-4ca5-8dab-916fd1d756df'	System	13 Jan 2021 00:30:40
User entered '12 Jan 2021 19:30:36'	System	13 Jan 2021 00:30:40

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-19T16:10:21', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6a24a3ec-22f1-456a-ac95-5c53c51ed8ce'	System	19 Jan 2021 21:10:31
User entered 'No (N)'	System	19 Jan 2021 21:10:31



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-01-19T16:10:24', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6a24a3ec-22f1-456a-ac95-5c53c51ed8ce'	System	19 Jan 2021 21:10:31
User entered 'No (N)'	System	19 Jan 2021 21:10:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-01-19T16:10:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6a24a3ec-22f1-456a-ac95-5c53c51ed8ce' User entered '19 Jan 2021 16:10:27'	System	19 Jan 2021 21:10:31
	System	19 Jan 2021 21:10:31

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-25T15:31:33', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96d8fba6-338e-40ae-96ae-a7eba4a2b443'	System	25 Jan 2021 20:31:42
User entered 'No (N)'	System	25 Jan 2021 20:31:42

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-01-25T15:31:36', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96d8fba6-338e-40ae-96ae-a7eba4a2b443'	System	25 Jan 2021 20:31:42
User entered 'No (N)'	System	25 Jan 2021 20:31:42

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-01-25T15:31:38', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96d8fba6-338e-40ae-96ae-a7eba4a2b443' User entered '25 Jan 2021 15:31:38'	System	25 Jan 2021 20:31:42
	System	25 Jan 2021 20:31:42



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-01-31T14:02:08', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e82637d5-2bc8-4f72-b7e4-6fec0dc7e89a'	System	31 Jan 2021 19:02:18
User entered 'No (N)'	System	31 Jan 2021 19:02:18

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-01-31T14:02:11', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e82637d5-2bc8-4f72-b7e4-6fec0dc7e89a'	System	31 Jan 2021 19:02:18
User entered 'No (N)'	System	31 Jan 2021 19:02:18

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-01-31T14:02:13', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'e82637d5-2bc8-4f72-b7e4-6fec0dc7e89a' User entered '31 Jan 2021 14:02:13'	System	31 Jan 2021 19:02:18
	System	31 Jan 2021 19:02:18

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-07T11:41:39', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972'	System	07 Feb 2021 16:42:23
User entered 'Yes (Y)'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-02-07T11:41:43', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972'	System	07 Feb 2021 16:42:23
User entered 'Yes (Y)'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-02-07T11:41:50', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972'	System	07 Feb 2021 16:42:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-07T11:41:56', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972'	System	07 Feb 2021 16:42:23
User entered 'No (N)'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-07T11:42:06', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972'	System	07 Feb 2021 16:42:23
User entered 'No (N)'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-02-07T11:42:09', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '98e14689-6c53-4460-8ce6-0b6b9670a972' User entered '07 Feb 2021 11:42:09'	System	07 Feb 2021 16:42:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-18T13:54:12', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered 'Yes (Y)'	System	18 Feb 2021 18:54:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-02-18T13:54:17', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered 'No (N)'	System	18 Feb 2021 18:54:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-18T13:54:20', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered 'No (N)'	System	18 Feb 2021 18:54:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-18T13:54:27', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered 'Yes (Y)'	System	18 Feb 2021 18:54:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-02-18T13:54:29', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Feb 2021 18:54:46

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-02-18T13:54:32', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c4287f17-6d54-4312-a0ee-9cf5e1a4ab45'	System	18 Feb 2021 18:54:46
User entered '18 Feb 2021 13:54:32'	System	18 Feb 2021 18:54:46



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-02-21T22:50:59', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96478b4e-2e85-4865-b813-f90df67e7b35'	System	22 Feb 2021 03:53:16
User entered 'No (N)'	System	22 Feb 2021 03:53:16

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-02-21T22:51:01', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96478b4e-2e85-4865-b813-f90df67e7b35'	System	22 Feb 2021 03:53:16
User entered 'No (N)'	System	22 Feb 2021 03:53:16

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-02-21T22:51:04', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '96478b4e-2e85-4865-b813-f90df67e7b35'	System	22 Feb 2021 03:53:16
User entered '21 Feb 2021 22:51:04'	System	22 Feb 2021 03:53:16

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-03-01T14:38:44-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8d434e66-2b34-4715-b371-d25ee419d4f0'	System	01 Mar 2021 19:38:51
User entered 'No (N)'	System	01 Mar 2021 19:38:51

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-03-01T14:38:46-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8d434e66-2b34-4715-b371-d25ee419d4f0'	System	01 Mar 2021 19:38:51
User entered 'No (N)'	System	01 Mar 2021 19:38:51

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-01T14:38:48-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8d434e66-2b34-4715-b371-d25ee419d4f0'	System	01 Mar 2021 19:38:51
User entered '01 Mar 2021 14:38:48'	System	01 Mar 2021 19:38:51

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-03-10T08:24:26-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99c0e5e7-5d75-43aa-915a-bcea338e3637'	System	10 Mar 2021 13:24:37
User entered 'No (N)'	System	10 Mar 2021 13:24:37



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-03-10T08:24:29-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99c0e5e7-5d75-43aa-915a-bcea338e3637'	System	10 Mar 2021 13:24:37
User entered 'No (N)'	System	10 Mar 2021 13:24:37

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-10T08:24:31-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '99c0e5e7-5d75-43aa-915a-bcea338e3637' User entered '10 Mar 2021 08:24:31'	System	10 Mar 2021 13:24:37
	System	10 Mar 2021 13:24:37

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-03-14T14:04:28-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c1cf99db-b730-41c7-9f32-aef0e6be0922'	System	14 Mar 2021 18:04:38
User entered 'No (N)'	System	14 Mar 2021 18:04:38

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-03-14T14:04:30-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c1cf99db-b730-41c7-9f32-aef0e6be0922'	System	14 Mar 2021 18:04:38
User entered 'No (N)'	System	14 Mar 2021 18:04:38

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-14T14:04:32-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'c1cf99db-b730-41c7-9f32-aef0e6be0922'	System	14 Mar 2021 18:04:38
User entered '14 Mar 2021 14:04:32'	System	14 Mar 2021 18:04:38



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-03-21T11:41:42-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4d68d95d-8eb7-47e0-bfb1-d7a5c5add0cd' User entered 'No (N)'	System	21 Mar 2021 15:41:49
	System	21 Mar 2021 15:41:49

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-03-21T11:41:44-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4d68d95d-8eb7-47e0-bfb1-d7a5c5add0cd'	System	21 Mar 2021 15:41:49
User entered 'No (N)'	System	21 Mar 2021 15:41:49

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-21T11:41:46-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '4d68d95d-8eb7-47e0-bfb1-d7a5c5add0cd' User entered '21 Mar 2021 11:41:46'	System	21 Mar 2021 15:41:49
	System	21 Mar 2021 15:41:49

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-03-29T10:01:41-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b8fc1441-2280-430d-83d0-c440d93df82e'	System	29 Mar 2021 14:01:48
User entered 'No (N)'	System	29 Mar 2021 14:01:48

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-03-29T10:01:43-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b8fc1441-2280-430d-83d0-c440d93df82e'	System	29 Mar 2021 14:01:48
User entered 'No (N)'	System	29 Mar 2021 14:01:48

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-29T10:01:45-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b8fc1441-2280-430d-83d0-c440d93df82e' User entered '29 Mar 2021 10:01:45'	System	29 Mar 2021 14:01:48
	System	29 Mar 2021 14:01:48

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-04-15T09:48:44-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6fb434b6-7c7b-4afa-9993-c3caa8fcc3f3'	System	15 Apr 2021 14:00:06
User entered 'No (N)'	System	15 Apr 2021 14:00:06

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-04-15T09:48:46-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6fb434b6-7c7b-4afa-9993-c3caa8fcc3f3'	System	15 Apr 2021 14:00:06
User entered 'No (N)'	System	15 Apr 2021 14:00:06

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-04-15T09:48:49-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '6fb434b6-7c7b-4afa-9993-c3caa8fcc3f3'	System	15 Apr 2021 14:00:06
User entered '15 Apr 2021 09:48:49'	System	15 Apr 2021 14:00:06

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-04-18T21:53:01-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5b9c1eda-d865-4c15-b945-65d704147b89'	System	19 Apr 2021 01:53:09
User entered 'No (N)'	System	19 Apr 2021 01:53:09

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-04-18T21:53:03-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5b9c1eda-d865-4c15-b945-65d704147b89'	System	19 Apr 2021 01:53:09
User entered 'No (N)'	System	19 Apr 2021 01:53:09

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-04-18T21:53:06-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '5b9c1eda-d865-4c15-b945-65d704147b89'	System	19 Apr 2021 01:53:09
User entered '18 Apr 2021 21:53:06'	System	19 Apr 2021 01:53:09

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-04-25T20:09:21-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b34010d0-eea3-4472-abd1-f6c9d9b2920d' User entered 'No (N)'	System	26 Apr 2021 00:09:33
	System	26 Apr 2021 00:09:33

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-04-25T20:09:26-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b34010d0-eea3-4472-abd1-f6c9d9b2920d' User entered 'No (N)'	System	26 Apr 2021 00:09:33



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-04-25T20:09:29-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: 'b34010d0-eea3-4472-abd1-f6c9d9b2920d' User entered '25 Apr 2021 20:09:29'	System	26 Apr 2021 00:09:33
	System	26 Apr 2021 00:09:33

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[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 (f1b8851738c92cf6)', Time: '2021-05-02T12:34:21-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2b908a51-fdd8-460b-a631-cd99432e0c53'	System	02 May 2021 16:34:41
User entered 'No (N)'	System	02 May 2021 16:34:41

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

Have you been exposed to someone with 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 (f1b8851738c92cf6)', Time: '2021-05-02T12:34:35-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2b908a51-fdd8-460b-a631-cd99432e0c53'	System	02 May 2021 16:34:41
User entered 'No (N)'	System	02 May 2021 16:34:41

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-05-02T12:34:38-04:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '2b908a51-fdd8-460b-a631-cd99432e0c53'	System	02 May 2021 16:34:41
User entered '02 May 2021 12:34:38'	System	02 May 2021 16:34:41

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:05:23



**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:05:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:05:23



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:05:23



**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:05:23

**US3052291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:05:23
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:05:23



US3052291

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:56:50**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-01T14:38:55-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8cd9f566-6580-46d4-8f9d-8e7bbf085416'	System	01 Mar 2021 19:39:30
User entered 'Yes (Y)'	System	01 Mar 2021 19:39:30

US3052291

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:56:50**

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-01T14:39:11-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8cd9f566-6580-46d4-8f9d-8e7bbf085416'	System	01 Mar 2021 19:39:30
User entered 'No (N)'	System	01 Mar 2021 19:39:30

**US3052291**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f1b8851738c92cf6)', Time: '2021-03-01T14:39:14-05:00', User OID: 'PatientReportedOutcome (US3052291)', ODM File OID: '8cd9f566-6580-46d4-8f9d-8e7bbf085416'	System	01 Mar 2021 19:39:30
User entered '01 Mar 2021 14:39:14'	System	01 Mar 2021 19:39:30

**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:03:45

**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:03:45

**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:03:45

**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:03:45

**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:48:38



**US3052291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:35:51
User entered 'I'	System	28 Dec 2020 21:48:38

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:48:53

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 21:48:53

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 21:48:53

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 21:48:53

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	04 Jan 2021 01:24:41
	(b) (4)	

**US3052291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User entered 'I'	System	04 Jan 2021 01:24:41

**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:15:23



**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:15:23

**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:15:23

**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:15:23

**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:15:29

**US3052291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User entered 'I'	System	21 Jan 2021 17:15:29

**US3052291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:56:51

US3052291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 09:09:36
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data corrected' (Site from System).		15 Mar 2021 02:59:19
User entered '9 Feb 2021' reason for change: Data Entry Error		15 Mar 2021 02:58:56
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 02:56:51
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Mar 2021 02:56:51

**US3052291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:56:51



**US3052291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:56:51

**US3052291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:37

**US3052291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:43:47
User entered '1'	System	12 Mar 2021 17:25:37

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:56

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:56

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:56

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'VISIT4'	System	12 Mar 2021 17:25:56

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44



**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '11:55'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered '10 Mar 2021 11:55'	System	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '83'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'bpm'	System	30 Mar 2021 18:15:44



**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'breaths/min'	System	30 Mar 2021 18:15:44

US3052291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:56:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '117'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'mmHg'	System	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '69'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'mmHg'	System	30 Mar 2021 18:15:44

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45



**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:26:43

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:26:43

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:27:01

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:27:01

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:47:22
User entered '12:43'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:27:01

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered '10 Mar 2021 12:43'	System	12 Mar 2021 17:27:01

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:15:50

**US3052291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:34:45
User entered 'I'	System	30 Mar 2021 18:15:50



**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:57:49

**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:41
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:57:49

**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:57:49

**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:41
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:57:49

**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:57:39

**US3052291**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:57:39

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:07:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:07:32



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:07:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 13:07:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:30

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:30

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:08:28



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:03:28
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:03:28
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '1'	System	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'I'	System	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '165' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '55' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '20.20202'	System	15 Jan 2021 13:10:32
DataPoint set to visible.	System	15 Jan 2021 13:08:28



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '165' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '55' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '20.20202'	System	15 Jan 2021 13:10:32
DataPoint set to visible.	System	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User accepted default value 'Pre-Dose (PREDOSE)'		15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14:45'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '14 Jan 2021 14:45'	System	15 Jan 2021 13:10:32



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '70'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'bpm'	System	15 Jan 2021 13:10:32

US3052291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'breaths/min'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '102'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'mmHg'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '70'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'mmHg'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '165' cm	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '55' kg	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '20.20202'	System	15 Jan 2021 13:10:32
DataPoint set to visible.	System	15 Jan 2021 13:08:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User accepted default value 'Post-Dose (POSTDOSE)'		15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '16:09'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered '14 Jan 2021 16:09'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '89'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'bpm'	System	15 Jan 2021 13:10:32



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'breaths/min'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '102'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'mmHg'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '69'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'mmHg'	System	15 Jan 2021 13:10:32

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:59

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:10:59



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:11:31

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered empty.	System	15 Jan 2021 13:11:31



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06

US3052291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'mRNA-1273'	System	15 Jan 2021 13:13:06
DataPoint set to visible.	System	15 Jan 2021 13:08:28

US3052291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06

US3052291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '15:37'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered '14 Jan 2021 15:37'	System	15 Jan 2021 13:13:06

US3052291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:06



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'ONCE'	System	15 Jan 2021 13:13:06

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 13:13:06

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '15:15'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered '14 Jan 2021 15:15'	System	15 Jan 2021 13:13:28

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:49

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:49



**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '15:19'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:49

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:50**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered '14 Jan 2021 15:19'	System	15 Jan 2021 13:13:49

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:13:56

**US3052291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'I'	System	15 Jan 2021 13:13:56

**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:12

US3052291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 09:08:45
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 02:55:12
User entered '30 Jan 2021'	(b) (4), (b) (6)	15 Mar 2021 02:55:12

**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:12

**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:12



**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:38:52

**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'I'	System	23 Feb 2021 21:38:52

**US3052291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'I'	System	23 Feb 2021 21:38:52
DataPoint set to visible.	System	23 Feb 2021 21:38:52

**US3052291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:34

**US3052291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:34

**US3052291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:40:34

**US3052291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'OLD29'	System	23 Feb 2021 21:40:34

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User accepted default value 'Pre-Dose (PREDOSE)'		23 Feb 2021 21:41:18



**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'No (N)'	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	



**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Feb 2021 21:41:18



**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'No (N)'	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18
	(b) (4), (b) (6)	



**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:18

**US3052291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'No (N)'	(b) (4)	23 Feb 2021 21:41:22



**US3052291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:41:22

**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:39

**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:39

**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:41:39

US3052291

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User closed query 'Per CDM: Subject had positive pregnancy test; therefore, is not receiving mRNA-1273 vaccine in OL, but per page 93 of PA7, "should be asked to remain in study and be followed up for safety". Please verify and confirm in site response if subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms will be distributed to study site to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:51
Query 'Per CDM: Subject had positive pregnancy test; therefore, is not receiving mRNA-1273 vaccine in OL, but per page 93 of PA7, "should be asked to remain in study and be followed up for safety". Please verify and confirm in site response if subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms will be distributed to study site to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7. ' answered with 'Per source Pt is still in study' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 17:32:55
User opened query 'Per CDM: Subject had positive pregnancy test; therefore, is not receiving mRNA-1273 vaccine in OL, but per page 93 of PA7, "should be asked to remain in study and be followed up for safety". Please verify and confirm in site response if subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms will be distributed to study site to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 20:20:24

US3052291

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

[Result](#)

Audit	User	Time (GMT)
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 14:59:59
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'subject tested twice and both test positive. ' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 21:42:21
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	23 Feb 2021 21:41:39
User entered 'Positive (POSITIVE)'	(b) (4), (b) (6)	23 Feb 2021 21:41:39

US3052291

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:56:50

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User closed query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:47:33
Query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' answered with 'updated' (Site from DM).	amy sheets (b) (4) (b) (4)	22 Mar 2021 19:11:31
User entered 'No (N)' reason for change: Data Entry Error	amy sheets (b) (4) (b) (4)	22 Mar 2021 19:11:08
User opened query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:33:46
User entered empty.		23 Feb 2021 21:41:39

**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	23 Feb 2021 21:41:39



**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	23 Feb 2021 21:41:39

**US3052291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:41:39

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'No (N)'	(b) (4)	23 Feb 2021 21:42:43

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Pregnancy (PREGNANCY)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:42:43

US3052291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 21:42:43

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:42:43
DataPoint set to visible.	System	23 Feb 2021 21:38:52

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:42:43
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:42:43
	(b) (4), (b) (6)	



**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:42:43

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4)	23 Feb 2021 21:42:43
	(b) (4), (b) (6)	

US3052291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:42:43

**US3052291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	23 Feb 2021 21:42:43

**US3052291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:31

**US3052291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'I'	System	15 Mar 2021 02:55:31

US3052291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	15 Mar 2021 23:45:04
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	15 Mar 2021 02:55:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 02:55:45

**US3052291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:45



**US3052291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered empty; reason for change Data Entry Error	amy sheets (b) (4)	15 Mar 2021 23:45:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	15 Mar 2021 02:55:45

**US3052291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'missed'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:45

**US3052291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 02:55:57

**US3052291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:43
User entered 'I'	System	15 Mar 2021 02:55:57

**US3052291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:02:39

**US3052291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '23 Mar 2021'	(b) (4)	25 Mar 2021 17:02:39
	(b) (4), (b) (6)	

**US3052291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:02:39

**US3052291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered 'OLD57'	System	25 Mar 2021 17:02:39



**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'No (N)'	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11



**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4)	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered empty.	System	25 Mar 2021 17:03:11

**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42



**US3052291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42

**US3052291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:03:34

**US3052291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:50**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:03:34

**US3052291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:04:09

**US3052291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:04:09

**US3052291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '15:51'	(b) (4), (b) (6)	25 Mar 2021 17:04:09

**US3052291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:47:42
User entered '23 Mar 2021 15:51'	System	25 Mar 2021 17:04:09

**US3052291**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:56:50**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:48:13



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:56:50

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:45
User closed query 'Per CDM Review: "Have you eve received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:41:23
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'subject had Botox injections in Aug. 2020 for migraines. already on medications list' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:52:08
User closed query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:56:10

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:56:50

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'patient was exposed to COVID no one else got it, roommate was positive. ' (Site from DM).	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:40:27
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:40:02
User opened query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 05:13:37
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	19 Mar 2021 16:46:42
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	14 Oct 2020 19:35:37

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:12:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 18:12:39
Data point term sent to Coder	System	05 Apr 2021 18:11:44
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 02:22:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 02:22:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 21:54:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 21:54:32
Data point term sent to Coder	System	03 Feb 2021 21:53:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	03 Feb 2021 21:52:56
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with '!' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 21:52:56
Coding entries removed.		03 Feb 2021 21:52:48
User entered 'FLONASE (Fluticasone)' reason for change: Data Entry Error		03 Feb 2021 21:52:48
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	03 Feb 2021 10:21:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:38:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:38:34
Data point term sent to Coder	System	14 Oct 2020 19:37:30
User entered 'Flonase'	Avia McClain-Stocker (b) (4)	14 Oct 2020 19:37:21

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:50

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 11:06:35
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:06:16
User entered 'Seasonal Allergies'	Avia McClain-Stocker (b) (4)	14 Oct 2020 19:37:21

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User entered '200' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'un'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'Other (OTHER)'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	



US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'unknown'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
User entered 'once daily (QD)'	(b) (4) Avia McClain-Stocker (b) (4)	14 Oct 2020 19:37:21

US3052291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered empty.	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:11:25
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered empty.	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'un Apr 2020'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered '0'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'Yes (Y)'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	



**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered empty.	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:46:42
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	14 Oct 2020 19:37:21
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:37:21

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:37:21

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:37:21

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Mar 2021 22:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 22:33:40
Data point term sent to Coder	System	24 Mar 2021 22:32:10
User entered 'botox'	amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'No (N)'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'migraines'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	



**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered '1'	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'Other (OTHER)'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'injection'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'other (OTHER)'	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

US3052291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'twice a year; last injection Aug 2020'	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered empty.	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30



**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'I'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'Yes (Y)'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
	(b) (4)	
User entered 'No (N)'	amy sheets (b) (4)	24 Mar 2021 22:31:30
	(b) (4)	

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:31:30

**US3052291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 22:31:30

US3052291

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:56:50**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	07 Apr 2021 15:43:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:05:42