

US3022063 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:51:44

All time stamps listed in this document are displayed in GMT

US3022063

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

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[Participant ID](#)

US3022063

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

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US3022063

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
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	False
Black	True
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) 23 Feb 2021 15:46:11

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Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 15:46:11

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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) 23 Feb 2021 15:46:12

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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) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	MORPHINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	IMITREX ALLERGY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	TORADOL ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	OBESITY
Start date (dd MMM yyyy)	29 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	BILATERAL LARGE PAINFUL BREAST
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	22 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

US3022063

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN MAR 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)	22 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

US3022063

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	08:08 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:08
Height ( <i>xxx.x</i> )	160.7 cm
Weight ( <i>xxx.x</i> )	103.5 kg
BMI ( <i>xxx.x</i> )	40.07824 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:12

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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) 23 Feb 2021 15:46:11

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Date of assessment (*dd MMM yyyy*) 29 JUL 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:12

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**Occupational Risk**

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**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)**

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**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) 23 Feb 2021 15:46:12

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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)	False
<b>Other</b>	True
<b>Specify</b>	LIVES IN A COMMUNITY WITH HIGH RISK PERSON TO PERSON CONTACT

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 142229

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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)	29 JUL 2020
Time of assessment (00:00-23:59)	08:08 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 08:08
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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)	29 JUL 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 10:53
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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.*

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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) 29 JUL 2020

What was the treatment time? (00:00-23:59) 10:17 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 10:17

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) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	09:04 (24 HR)
Collection date and time (derived)	29 JUL 2020 09:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:57	29 JUL 2020 08:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**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

98.9 °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

29 JUL 2020 10:49

PC Open Date & Time

29 JUL 2020 10:47

PC Close Date & Time

29 JUL 2020 13:17

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**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

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 29 JUL 2020 14:02

PC Close Date & Time 30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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**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

97.6 °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

30 JUL 2020 20:29

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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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

97.3 °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

31 JUL 2020 13:18

---

PC Open Date & Time

31 JUL 2020 12:00

---

PC Close Date & Time

01 AUG 2020 11:59

---

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

01 AUG 2020 18:40

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

02 AUG 2020 19:20

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 19:24

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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

05 AUG 2020 08:06

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 10:49

PC Open Date & Time

29 JUL 2020 10:47

PC Close Date & Time

29 JUL 2020 13:17

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**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 ☐

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.**

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

PC Open Date & Time

29 JUL 2020 14:02

PC Close Date & Time

30 JUL 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**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

30 JUL 2020 20:30

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**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

31 JUL 2020 13:18

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**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

01 AUG 2020 18:41

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**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

02 AUG 2020 19:21

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**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

03 AUG 2020 19:24

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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

05 AUG 2020 08:07

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**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 ☐

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 10:49
PC Open Date & Time	29 JUL 2020 10:47
PC Close Date & Time	29 JUL 2020 13:17

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**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 ☐

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 14:02

PC Close Date & Time

30 JUL 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1962

EAB) (1725)

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 20:30
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 1962

EAB) (1725)

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 13:19
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**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

56 of 1962

EAB) (1725)

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 18:41
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**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

58 of 1962

EAB) (1725)

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 19:22
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**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 ☒

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 19:25
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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 ☒

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 08:07
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59



US3022063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT2

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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)	27 AUG 2020
Time of assessment (00:00-23:59)	07:59 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 07:59
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG



US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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)	27 AUG 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:44
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3022063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 09:17 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 09:17

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

US3022063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	08:08 (24 HR)
Collection date and time (derived)	27 AUG 2020 08:08

US3022063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:21	27 AUG 2020 08:21
Nasopharyngeal Swab 2	No		

US3022063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**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

98.3 °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

27 AUG 2020 09:48

PC Open Date & Time

27 AUG 2020 09:37

PC Close Date & Time

27 AUG 2020 12:07

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	27 AUG 2020 20:07
PC Open Date & Time	27 AUG 2020 13:02
PC Close Date & Time	28 AUG 2020 11:59



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 22:15

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**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

29 AUG 2020 17:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:37

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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

97.7 °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

02 SEP 2020 21:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 09:48

PC Open Date & Time

27 AUG 2020 09:37

PC Close Date & Time

27 AUG 2020 12:07

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**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

27 AUG 2020 20:07

PC Open Date & Time

27 AUG 2020 13:02

PC Close Date & Time

28 AUG 2020 11:59



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**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

28 AUG 2020 22:15

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**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

29 AUG 2020 17:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**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

30 AUG 2020 19:37

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**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

31 AUG 2020 20:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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

02 SEP 2020 21:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**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 ☐

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 09:49
PC Open Date & Time	27 AUG 2020 09:37
PC Close Date & Time	27 AUG 2020 12:07



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**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 ☐

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 20:08
PC Open Date & Time	27 AUG 2020 13:02
PC Close Date & Time	28 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**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 ☒

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 22:16
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 17:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**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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US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:37
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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 ☒

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:42
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**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 ☒

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:46
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3022063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 08:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3022063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

08:26 (24 HR)

Collection date and time (derived)

01 OCT 2020 08:26



US3022063

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 OCT 2020 17:45:16

Patient Cloud Open Date & Time

28 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 18:51:53

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 17:38:40

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59



US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 04:14:59

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 20:41:10

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 08:26:52

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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 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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2020 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 14:15:47

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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 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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

---

22 DEC 2020 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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

27 DEC 2020 09:45:32

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 14:46:54

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 05:19:56

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 20:08:56

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 07:50:13

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 13:13:10

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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

07 FEB 2021 00:39:01

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 10:05:51

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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

20 FEB 2021 08:41:27

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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

26 FEB 2021 13:29:56

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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

06 MAR 2021 05:58:00

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 12:02:40

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 20:53:46

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

<b>TIMEPOINT</b>	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 16:10:11
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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 <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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59
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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59
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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59



US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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="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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59
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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

**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 ☐

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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 <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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3022063

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3022063

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:51:44

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 07:11:36

US3022063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3022063

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	VISIT4



US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:12:37

Generated On: 09 Jun 2021 14:51:44

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) \_\_\_\_\_

US3022063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3022063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:55:55

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00-23:59)	08:17 (24 HR)
Collection date and time (derived)	11 FEB 2021 08:17

US3022063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:46:12

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 23:01:29

Generated On: 09 Jun 2021 14:51:44

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3022063

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:01:29

Generated On: 09 Jun 2021 14:51:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022063**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

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*

**US3022063**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3022063

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:51:44

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"/>

**US3022063**

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

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

**Generated On: 09 Jun 2021 14:51:44**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3022063

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

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

Visit date (dd MMM yyyy)	13 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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US3022063

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:12:37

Generated On: 09 Jun 2021 14:51:44

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 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> )	13 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 type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3022063

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

08:27 (24 HR)

Collection date and time (derived)

13 JAN 2021 08:27

US3022063

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	08:35
Collection Date and Time (derived)	13 JAN 2021 08:35

US3022063

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 11:15:33

Generated On: 09 Jun 2021 14:51:44

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3022063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

AEID	USA-US051-2021-MRNA-1273-P30 1000001
Adverse event	WORSENING OF BILATERAL LARGE PAINFUL BREAST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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US3022063

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD A PREPLANNED SURGERY DUE TO PAINFUL BREAST. SUBJECT STATED THAT SHE HAD PAINFUL BREAST SINCE UN/UN/2004
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**US3022063**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (b) (4) 03 May 2021 12:40:45**

**Generated On: 09 Jun 2021 14:51:44**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3022063

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

AEID	USA-US051-2021-MRNA-1273-P30 1000001
Adverse event	WORSENING OF INGUINAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 JUN 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3022063

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

---

SUBJECT HAD A INGUINAL  
HERNIA SINCE MARCH OF 2010.  
SUBJECT STATED THAT SHE  
DIDN'T WANT SURGERY AT  
THE TIME. SUBJECT HAD  
SURGERY WITH ANOTHER  
SURGERY ON THE SAME DAY.  
SURGERY WAS AT CANDLER  
HOSPITAL.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

---

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

Yes ☒

No ☐

---

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

---

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Name of Medication ATORVASTAIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 15:46:11

Generated On: 09 Jun 2021 14:51:44

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 11:15:33

Generated On: 09 Jun 2021 14:51:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 OCT 2020	BREAST REDUCTION SURGERY	Medical History	
21 OCT 2020	WORSENING OF INGUINAL HERNIA REPAIR	Medical History	
21 OCT 2020	PANNICULECTOMY	Medical History	

US3022063

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:51:44

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

US3022063

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:51:44

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 ☐



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/JAN/2021 11:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/JAN/2021 07:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/JAN/2021 18:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/FEB/2021 17:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/APR/2021 12:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 12:40:45

Generated On: 09 Jun 2021 14:51:44

SAEID	USA-US051-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/APR/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022063 (Prod: Meridian Clinical Research-Savannah)



**US3022063**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:51:44**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:20:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'US3022063'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 11:59:13

**US3022063**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:03:41
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 14:28:09

**US3022063**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:03:41
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 11:59:14

**US3022063**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:03:41
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	29 Jul 2020 14:28:09

**US3022063**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'SCRN'	System	29 Jul 2020 14:28:09

US3022063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	12 Aug 2020 14:04:14
User entered (b) (6) 1962'	(b) (4), (b) (6)	29 Jul 2020 11:59:15
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	
	(b) (4)	

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '58'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'YEARS'	System	29 Jul 2020 14:29:07



**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '58'	System	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered 'Female (F)'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

US3022063

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:51:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered 'I'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07



**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

**US3022063**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:51:44**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:14
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 14:29:07

US3022063

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:51:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:10:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:10:39
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered '29 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jul 2020'	System	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2020'	System	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4)	29 Jul 2020 14:30:17



**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 14:30:17

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:04:56
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 11:59:14

**US3022063**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:51:44**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'I'	System	29 Jul 2020 14:30:24

**US3022063**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 14:51:44**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:05:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 14:30:24

US3022063

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:51:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Subjects medical history of Post menopausal missing with onset date of unk/unk/2010. Pleae update eCRF. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:40:58
Query 'Subjects medical history of Post menopausal missing with onset date of unk/unk/2010. Pleae update eCRF. ' answered with 'updated' (Site from CRA).	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 21:27:47
User opened query 'Subjects medical history of Post menopausal missing with onset date of unk/unk/2010. Pleae update eCRF. ' (Site from CRA).	(b) (4), (b) (6)	12 Aug 2020 14:15:36
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:05:13
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:42:32



US3022063

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:51:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
Data point term sent to Coder	System	23 Feb 2021 15:46:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
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)	04 Sep 2020 11:14:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 11:14:48
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 21:59:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 21:59:48
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:55
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:47
Data point term sent to Coder	System	29 Jul 2020 15:43:37
User entered 'MORPHINE ALLERGY'	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:58
User entered 'UN UNK 2005'	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:56
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:00
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:02
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:04
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 2005'	System	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2005'	System	29 Jul 2020 15:42:57



**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:42:57

**US3022063**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:42:57

US3022063

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:51:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:02
Data point term sent to Coder	System	23 Feb 2021 15:46:14
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:12
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:35
Data point term sent to Coder	System	29 Jul 2020 15:43:37
User entered 'IMITREX ALLERGY'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:13
User entered 'UN UNK 1990'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:21
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:16
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:18
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:19
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:12



**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 1990'	System	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '1990'	System	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:12

**US3022063**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:12

US3022063

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:51:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:02
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:29
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: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:41:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:41:05
Data point term sent to Coder	System	29 Jul 2020 15:43:39
User entered 'TORADOL ALLERGY'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:32
User entered 'UN UNK 2000'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:35
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:34
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:28



**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:36
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:37
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 2000'	System	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2000'	System	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:28

**US3022063**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:28

US3022063

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:51:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:00
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:27
Data point term sent to Coder	System	29 Jul 2020 15:44:40
User entered 'HYPERCHOLESTEROLEMIA'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:46
User entered 'UN UNK 2000'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:41



**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:47
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:49
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:50
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:52
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 2000'	System	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2000'	System	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:41

**US3022063**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:41



US3022063

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:51:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:00
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:58
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:24
Data point term sent to Coder	System	29 Jul 2020 15:44:39
User entered 'MIGRAINES'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:11:59
User entered 'UN UNK 1980'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:12:01
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:12:05
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:12:03
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:12:07
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 1980'	System	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '1980'	System	29 Jul 2020 15:43:51



**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:51

**US3022063**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	29 Jul 2020 15:43:51

US3022063

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:51:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:02:02
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:29:41
Data point term sent to Coder	System	24 Aug 2020 21:28:22
User entered 'post menopausal'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User entered 'un UNK 2010'	Stella Yoon (b) (4)	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:53:29
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 21:27:40



**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 2010'	System	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2010'	System	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	24 Aug 2020 21:27:40

**US3022063**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	24 Aug 2020 21:27:40

US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:04
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 13:24:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 13:24:42
Data point term sent to Coder	System	07 Dec 2020 13:23:56
User entered 'obesity'	(b) (4), (b) (6)	07 Dec 2020 13:23:20

US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '29 Jul 2020'	(b) (4), (b) (6)	07 Dec 2020 13:23:20

US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 13:23:20

US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 13:23:20



US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 13:23:20

US3022063

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 13:23:20

**US3022063**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jul 2020'	System	07 Dec 2020 13:23:20

**US3022063**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2020'	System	07 Dec 2020 13:23:20

**US3022063**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	07 Dec 2020 13:23:20

**US3022063**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered empty.	System	07 Dec 2020 13:23:20

US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Painful breasts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:17:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 16:17:01
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Painful breasts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 12:22:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 12:22:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Painful breasts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 12:06:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 12:06:11
Data point term sent to Coder	System	15 Jan 2021 18:47:31
User entered 'bilateral large painful breast'	(b) (4), (b) (6)	15 Jan 2021 18:46:52

US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'un UNK 2004'	(b) (4), (b) (6)	15 Jan 2021 18:46:52



US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 18:46:52

US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 18:46:52

US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '22 Oct 2020'	(b) (4), (b) (6)	15 Jan 2021 18:46:52

US3022063

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 18:46:52

**US3022063**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Jan 2004'	System	15 Jan 2021 18:46:52

**US3022063**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2004'	System	15 Jan 2021 18:46:52

**US3022063**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Oct 2020'	System	15 Jan 2021 18:46:52

**US3022063**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2020'	System	15 Jan 2021 18:46:52



**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53



**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

**US3022063**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:02
Data point term sent to Coder	System	23 Feb 2021 15:46:17
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:47:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 18:47:57
Data point term sent to Coder	System	15 Jan 2021 18:47:32
User entered 'inguinal hernia'	(b) (4), (b) (6)	15 Jan 2021 18:47:14

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'un Mar 2010'	(b) (4), (b) (6)	15 Jan 2021 18:47:14

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 18:47:14

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Jan 2021 18:47:14

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '22 Oct 2020'	(b) (4), (b) (6)	15 Jan 2021 18:47:14

US3022063

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:51:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	(b) (4), (b) (6)	15 Jan 2021 18:47:14



**US3022063**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Mar 2010'	System	15 Jan 2021 18:47:14

**US3022063**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:51:44**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2010'	System	15 Jan 2021 18:47:14

**US3022063**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'Oct 2020'	System	15 Jan 2021 18:47:14

**US3022063**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:51:44**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '2020'	System	15 Jan 2021 18:47:14

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:13
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:13
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38

US3022063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Query 'Per the source, there is no time indicated. Please reconcile or clarify. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:36:14
User opened query 'Per the source, there is no time indicated. Please reconcile or clarify. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:16:31
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:09:11
User entered '08:08'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:44:38

**US3022063**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered '29 Jul 2020 08:08'	System	29 Jul 2020 15:44:38



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:05:37
User entered '160.7' cm	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
DataPoint set to visible.	System	29 Jul 2020 14:30:24

US3022063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:05:40
User entered '103.5' kg	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
DataPoint set to visible.	System	29 Jul 2020 14:30:24

US3022063

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
Query 'Per the source, BMI us 40.1 kg/m2. Please reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:03:55
User opened query 'Per the source, BMI us 40.1 kg/m2. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:22:48
Amendment Manager: User entered '40.07824'	System	16 Sep 2020 23:37:51
User entered '40.1'	System	29 Jul 2020 15:44:38
DataPoint set to visible.	System	29 Jul 2020 14:30:24

**US3022063**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'kg/m2'	System	29 Jul 2020 15:44:38
DataPoint set to visible.	System	29 Jul 2020 14:30:24

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:54:36
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 15:26:28
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:05:37
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:09:31
User entered '37.0' C	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:09:33
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
	(b) (4)	

**US3022063**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:13
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:09:20
User entered '65'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
	(b) (4)	



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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'bpm'	System	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:09:42
User entered '15'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'breaths/min'	System	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:13
User entered '138'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
	(b) (4)	

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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'mmHg'	System	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:50:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:10:13
User entered '94'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:38
	(b) (4)	

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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User entered 'mmHg'	System	29 Jul 2020 15:44:38

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Per the source, physical exam was performed. Please update. ' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:48:16
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:48:13
Query 'Per the source, physical exam was performed. Please update. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:34:46
DataPoint Un-verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:34:34
Protocol deviation 'Physical exam required at screening and not performed.' inactivated.	(b) (4), (b) (6)	10 Nov 2020 21:05:49
User opened query 'Per the source, physical exam was performed. Please update. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:32:04
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:54:26
Protocol deviation created: Physical exam required at screening and not performed. Class: Incl/Excl Criteria not met Code: Deviation.	(b) (4), (b) (6)	30 Sep 2020 13:54:22
DataPoint Un-verified.	Shanice Bennett (b) (4)	27 Aug 2020 18:49:04
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	27 Aug 2020 18:49:04
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:46

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Please provide date of the physical exam.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:48:18
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:48:15
Query 'Please provide date of the physical exam.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:34:40
DataPoint Un-verified.	(b) (4) Shanice Bennett (b) (4)	13 Nov 2020 13:34:34
User entered '29 Jul 2020' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	13 Nov 2020 13:34:34
User opened query 'Please provide date of the physical exam.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:32:30
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:54:26
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 18:49:04
DataPoint Un-verified.	Shanice Bennett (b) (4)	27 Aug 2020 18:49:04
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	27 Aug 2020 18:49:04
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 14:03:38
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:44:46

**US3022063**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:51:44**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

US3022063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

US3022063

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:44

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

**US3022063**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:51:44**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

**US3022063**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04



**US3022063**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:51:44**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:51:44

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered 'UN UNK 2010'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:51:44**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:08:21
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:04

US3022063

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:44

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:44

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Jul 2020 15:45:54
	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:44

**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:44

**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54



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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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[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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Jul 2020 15:45:54
	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54
	(b) (4)	

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:46:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:46:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:46:07
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:45:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:45:54

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:51:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Form: Risk of Exposure

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**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

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**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)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:51:44**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'I'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:17:48
User entered 'LIVES IN A COMMUNITY WITH HIGH RISK PERSON TO PERSON CONTACT'	Shanice Bennett (b) (4)	29 Jul 2020 15:45:54



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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:18:51
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:17

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:18:51
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:17

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

[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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:18:51
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:46:20
User entered 'Home (Home)'	(b) (4)	29 Jul 2020 15:46:17

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'VISIT1'	System	29 Jul 2020 15:46:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 13:09:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:51:44

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:12:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:12:06
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 13:09:17
User entered '142229' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 13:09:17
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	22 Aug 2020 01:43:13
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	12 Aug 2020 23:22:00
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 13:09:17

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Folder: Visit 1 Day 1

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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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:33



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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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:33

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Folder: Visit 1 Day 1

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Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:15:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	22 Aug 2020 01:43:13
DataPoint Un-verified.	Shanice Bennett (b) (4)	12 Aug 2020 23:22:00
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	12 Aug 2020 23:22:00
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:33

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**Folder: Visit 1 Day 1**

**Form: Randomization**

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:33

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:51:44**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:21:07
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:46:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:37
	(b) (4), (b) (6)	
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:53:57
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 15:23:58
DataPoint Un-verified.	(b) (4)	
	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 15:23:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:49:18
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:22:18
User entered '160.7' cm	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:39
	(b) (4), (b) (6)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 14:22:19
User entered '103.5' kg	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:37
	(b) (4), (b) (6)	
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:53:57
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 15:23:58
DataPoint Un-verified.	(b) (4)	
	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 15:23:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:49:18
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:22:18
User entered '160.7' cm	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:39
	(b) (4), (b) (6)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 14:22:19
User entered '103.5' kg	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '08:08'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '29 Jul 2020 08:08'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '37.0' C	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

US3022063

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '65'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'bpm'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '15'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'breaths/min'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '138'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '94'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	29 Jul 2020 15:47:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:37
	(b) (4), (b) (6)	
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 08:53:57
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 15:23:58
DataPoint Un-verified.	(b) (4)	
	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 15:23:52
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:49:18
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:22:18
User entered '160.7' cm	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:51:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 17:41:39
	(b) (4), (b) (6)	
DataPoint Un-verified.	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:23:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Aug 2020 14:22:19
User entered '103.5' kg	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:22:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:22:23
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:57:22
User closed query 'Per CDM: the treatment time on the Exposure CRF is 10:27. The Vital Signs Post Dose Time of Assessment is 10:53. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.	(b) (4), (b) (6)	27 Aug 2020 06:34:56
' (Site from DM).		
User entered '10:53' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 18:13:06
Query 'Per CDM: the treatment time on the Exposure CRF is 10:27. The Vital Signs Post Dose Time of Assessment is 10:53. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.	Shanice Bennett (b) (4)	26 Aug 2020 17:31:11
' answered with 'UPDATED' (Site from DM).		
DataPoint Un-verified.	Shanice Bennett (b) (4)	26 Aug 2020 17:31:07
User entered '10:57' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:31:07
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:59:30
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		12 Aug 2020 23:20:32
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 13:26:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Query 'Per CDM: the treatment time on the Exposure CRF is 10:27.The Vital Signs Post Dose Time of Assessment is 10:53. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.   ' canceled (Site from DM).	(b) (4), (b) (6)	06 Aug 2020 09:09:53
User opened query 'Per CDM: the treatment time on the Exposure CRF is 10:27.The Vital Signs Post Dose Time of Assessment is 10:53. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.	(b) (4), (b) (6)	06 Aug 2020 09:06:14
' (Site from DM).		
User opened query 'Per CDM: the treatment time on the Exposure CRF is 10:27. The Vital Signs Post Dose Time of Assessment is 10:53. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.	(b) (4), (b) (6)	05 Aug 2020 16:24:42
' (Site from DM).		
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT' (Site from System).	Shanice Bennett (b) (4)	29 Jul 2020 15:48:07
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	29 Jul 2020 15:47:59
User entered '10:53'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '29 Jul 2020 10:53'	System	26 Aug 2020 18:13:06
User entered '29 Jul 2020 10:57'	System	26 Aug 2020 17:31:07
User entered '29 Jul 2020 10:53'	System	29 Jul 2020 15:47:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '37.2' C	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '65'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'bpm'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '15'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'breaths/min'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '136'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59



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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:26:12
User entered '84'	Shanice Bennett (b) (4)	29 Jul 2020 15:47:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	29 Jul 2020 15:47:59

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Per the eCRF guidelines, Physical exam should be marked as No in visit 1 day folder. Please update. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:47:57
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:47:55
Query 'Per the eCRF guidelines, Physical exam should be marked as No in visit 1 day folder. Please update. ' answered with 'updated' (Site from CRA). DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 13:35:05
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 13:35:00
User opened query 'Per the eCRF guidelines, Physical exam should be marked as No in visit 1 day folder. Please update. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:07:41
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:28:19
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:48:15

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	14 Jan 2021 15:47:59
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	13 Nov 2020 13:35:00
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:35:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:28:19
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:15
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:24:33
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:51:44**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:24:35
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:24:36
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33



US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:25:08
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:57:40
User closed query 'Per source, treatment time is noted as 10:17. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 13:40:42
Query 'Per source, treatment time is noted as 10:17. Please confirm and update as needed.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	12 Aug 2020 23:20:36
User entered '10:17' reason for change: Data Entry Error	(b) (4)	12 Aug 2020 23:20:32
User opened query 'Per source, treatment time is noted as 10:17. Please confirm and update as needed.' (Site from CRA).	(b) (4), (b) (6)	12 Aug 2020 14:30:51
User entered '10:27'	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '29 Jul 2020 10:17'	System	12 Aug 2020 23:20:32
User entered '29 Jul 2020 10:27'	System	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:57:40
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4)	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 13:57:40
User entered 'ONCE'	System	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 14:31:33

US3022063

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:20:01
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:40



**US3022063**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:20:01
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:40

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:20:01
User entered '09:04'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:40

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '29 Jul 2020 09:04'	System	29 Jul 2020 15:48:40

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:29
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

US3022063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:29
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:29
User entered '08:57'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '29 Jul 2020 08:57'	System	29 Jul 2020 15:48:54



**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

US3022063

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:29
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:29
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:48:54

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered empty.	System	29 Jul 2020 15:48:54

US3022063

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 14:35:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:52:34

**US3022063**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	29 Jul 2020 15:52:34

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:48:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '978f5e99-dced-483f-9710-49257c4a0a19'	System	29 Jul 2020 14:49:12
User entered 'Yes (Y)'	System	29 Jul 2020 14:49:12



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:48:57', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '978f5e99-dced-483f-9710-49257c4a0a19'	System	29 Jul 2020 14:49:12
User entered '98.9'	System	29 Jul 2020 14:49:12

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:01', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '978f5e99-dced-483f-9710-49257c4a0a19'	System	29 Jul 2020 14:49:12
User entered 'No (N)'	System	29 Jul 2020 14:49:12

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:05', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '978f5e99-dced-483f-9710-49257c4a0a19'	System	29 Jul 2020 14:49:12
User entered '29 Jul 2020 10:49'	System	29 Jul 2020 14:49:12

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 14:02'	System	12 Aug 2020 23:20:32
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 2'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '06813560-32c7-4121-b067-93450fd38e4c'	System	31 Jul 2020 00:29:32
User entered 'Yes (Y)'	System	31 Jul 2020 00:29:32



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '06813560-32c7-4121-b067-93450fd38e4c'	System	31 Jul 2020 00:29:32
User entered '97.6'	System	31 Jul 2020 00:29:32

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '06813560-32c7-4121-b067-93450fd38e4c'	System	31 Jul 2020 00:29:32
User entered 'No (N)'	System	31 Jul 2020 00:29:32

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:27', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '06813560-32c7-4121-b067-93450fd38e4c'	System	31 Jul 2020 00:29:32
User entered '30 Jul 2020 20:29'	System	31 Jul 2020 00:29:32

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 3'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:25', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d4141bf-0495-43a6-839c-078ed9f3954d'	System	31 Jul 2020 17:18:47
User entered 'Yes (Y)'	System	31 Jul 2020 17:18:47

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d4141bf-0495-43a6-839c-078ed9f3954d' User entered '97.3'	System	31 Jul 2020 17:18:47
	System	31 Jul 2020 17:18:47



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d4141bf-0495-43a6-839c-078ed9f3954d'	System	31 Jul 2020 17:18:47
User entered 'No (N)'	System	31 Jul 2020 17:18:47

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d4141bf-0495-43a6-839c-078ed9f3954d'	System	31 Jul 2020 17:18:47
User entered '31 Jul 2020 13:18'	System	31 Jul 2020 17:18:47

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 4'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:40:46', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5c4b37cc-45ea-45d0-8deb-303c5b59183e'	System	01 Aug 2020 22:41:04
User entered 'Yes (Y)'	System	01 Aug 2020 22:41:04

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:40:50', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5c4b37cc-45ea-45d0-8deb-303c5b59183e'	System	01 Aug 2020 22:41:04
User entered '98.2'	System	01 Aug 2020 22:41:04

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:40:55', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5c4b37cc-45ea-45d0-8deb-303c5b59183e'	System	01 Aug 2020 22:41:04
User entered 'No (N)'	System	01 Aug 2020 22:41:04



**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:40:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5c4b37cc-45ea-45d0-8deb-303c5b59183e'	System	01 Aug 2020 22:41:04
User entered '01 Aug 2020 18:40'	System	01 Aug 2020 22:41:04

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 5'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:20:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0a696310-e04c-4b1e-95a2-092fd9ff95ed'	System	02 Aug 2020 23:20:55
User entered 'Yes (Y)'	System	02 Aug 2020 23:20:55

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:20:38', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0a696310-e04c-4b1e-95a2-092fd9ff95ed'	System	02 Aug 2020 23:20:55
User entered '98.3'	System	02 Aug 2020 23:20:55

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:20:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0a696310-e04c-4b1e-95a2-092fd9ff95ed'	System	02 Aug 2020 23:20:55
User entered 'No (N)'	System	02 Aug 2020 23:20:55

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:20:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0a696310-e04c-4b1e-95a2-092fd9ff95ed'	System	02 Aug 2020 23:20:55
User entered '02 Aug 2020 19:20'	System	02 Aug 2020 23:20:55



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 6'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:23:58', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '8b27acf2-5e81-40ac-9829-c96c386550d9'	System	03 Aug 2020 23:24:29
User entered 'Yes (Y)'	System	03 Aug 2020 23:24:29

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '8b27acf2-5e81-40ac-9829-c96c386550d9'	System	03 Aug 2020 23:24:29
User entered '97.6'	System	03 Aug 2020 23:24:29

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '8b27acf2-5e81-40ac-9829-c96c386550d9'	System	03 Aug 2020 23:24:29
User entered 'No (N)'	System	03 Aug 2020 23:24:29

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:25', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '8b27acf2-5e81-40ac-9829-c96c386550d9'	System	03 Aug 2020 23:24:29
User entered '03 Aug 2020 19:24'	System	03 Aug 2020 23:24:29

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 7'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:35', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a74500ff-cba7-4534-84ca-76cfd6c1b5d7'	System	05 Aug 2020 12:06:50
User entered 'Yes (Y)'	System	05 Aug 2020 12:06:50

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a74500ff-cba7-4534-84ca-76cfd6c1b5d7'	System	05 Aug 2020 12:06:50
User entered '97.6'	System	05 Aug 2020 12:06:50

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:43', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a74500ff-cba7-4534-84ca-76cfd6c1b5d7'	System	05 Aug 2020 12:06:50
User entered 'No (N)'	System	05 Aug 2020 12:06:50

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:46', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a74500ff-cba7-4534-84ca-76cfd6c1b5d7'	System	05 Aug 2020 12:06:50
User entered '05 Aug 2020 08:06'	System	05 Aug 2020 12:06:50

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '633ec66f-f2b8-46b6-879b-3c213bdede22'	System	29 Jul 2020 14:49:36
User entered 'None (1)'	System	29 Jul 2020 14:49:36

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:20', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '633ec66f-f2b8-46b6-879b-3c213bdede22'	System	29 Jul 2020 14:49:36
User entered 'No (N)'	System	29 Jul 2020 14:49:36

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '633ec66f-f2b8-46b6-879b-3c213bdede22'	System	29 Jul 2020 14:49:36
User entered 'No (N)'	System	29 Jul 2020 14:49:36

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:27', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '633ec66f-f2b8-46b6-879b-3c213bdede22'	System	29 Jul 2020 14:49:36
User entered 'None (1)'	System	29 Jul 2020 14:49:36

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '633ec66f-f2b8-46b6-879b-3c213bdede22'	System	29 Jul 2020 14:49:36
User entered '29 Jul 2020 10:49'	System	29 Jul 2020 14:49:36

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 14:02'	System	12 Aug 2020 23:20:32
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 2'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b43c2cc2-d774-42b7-b614-2c630a2c26a4'	System	31 Jul 2020 00:30:04
User entered 'None (1)'	System	31 Jul 2020 00:30:04

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:47', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b43c2cc2-d774-42b7-b614-2c630a2c26a4'	System	31 Jul 2020 00:30:04
User entered 'No (N)'	System	31 Jul 2020 00:30:04

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:49', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b43c2cc2-d774-42b7-b614-2c630a2c26a4'	System	31 Jul 2020 00:30:04
User entered 'No (N)'	System	31 Jul 2020 00:30:04

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:29:53', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b43c2cc2-d774-42b7-b614-2c630a2c26a4'	System	31 Jul 2020 00:30:04
User entered 'None (1)'	System	31 Jul 2020 00:30:04

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b43c2cc2-d774-42b7-b614-2c630a2c26a4'	System	31 Jul 2020 00:30:04
User entered '30 Jul 2020 20:30'	System	31 Jul 2020 00:30:04



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 3'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '40b2e0ca-6a33-41d6-b7ec-5a1363aaad64'	System	31 Jul 2020 17:19:03
User entered 'None (1)'	System	31 Jul 2020 17:19:03

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '40b2e0ca-6a33-41d6-b7ec-5a1363aaad64'	System	31 Jul 2020 17:19:03
User entered 'No (N)'	System	31 Jul 2020 17:19:03

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '40b2e0ca-6a33-41d6-b7ec-5a1363aaad64'	System	31 Jul 2020 17:19:03
User entered 'No (N)'	System	31 Jul 2020 17:19:03

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:55', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '40b2e0ca-6a33-41d6-b7ec-5a1363aaad64'	System	31 Jul 2020 17:19:03
User entered 'None (1)'	System	31 Jul 2020 17:19:03

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:18:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '40b2e0ca-6a33-41d6-b7ec-5a1363aaad64'	System	31 Jul 2020 17:19:03
User entered '31 Jul 2020 13:18'	System	31 Jul 2020 17:19:03



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 4'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:04', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f732dfa7-45c1-430d-9c2c-0ec6ef032217'	System	01 Aug 2020 22:41:23
User entered 'None (1)'	System	01 Aug 2020 22:41:23

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f732dfa7-45c1-430d-9c2c-0ec6ef032217'	System	01 Aug 2020 22:41:23
User entered 'No (N)'	System	01 Aug 2020 22:41:23

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f732dfa7-45c1-430d-9c2c-0ec6ef032217'	System	01 Aug 2020 22:41:23
User entered 'No (N)'	System	01 Aug 2020 22:41:23

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f732dfa7-45c1-430d-9c2c-0ec6ef032217'	System	01 Aug 2020 22:41:23
User entered 'None (1)'	System	01 Aug 2020 22:41:23

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f732dfa7-45c1-430d-9c2c-0ec6ef032217'	System	01 Aug 2020 22:41:23
User entered '01 Aug 2020 18:41'	System	01 Aug 2020 22:41:23



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 5'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:20:55', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c0e1fa54-b588-42f8-bd0b-17188a3583e7'	System	02 Aug 2020 23:21:26
User entered 'None (1)'	System	02 Aug 2020 23:21:26

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:08', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c0e1fa54-b588-42f8-bd0b-17188a3583e7'	System	02 Aug 2020 23:21:26
User entered 'No (N)'	System	02 Aug 2020 23:21:26

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c0e1fa54-b588-42f8-bd0b-17188a3583e7'	System	02 Aug 2020 23:21:26
User entered 'No (N)'	System	02 Aug 2020 23:21:26

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:15', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c0e1fa54-b588-42f8-bd0b-17188a3583e7'	System	02 Aug 2020 23:21:26
User entered 'None (1)'	System	02 Aug 2020 23:21:26

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c0e1fa54-b588-42f8-bd0b-17188a3583e7'	System	02 Aug 2020 23:21:26
User entered '02 Aug 2020 19:21'	System	02 Aug 2020 23:21:26



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 6'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '19f0d75d-f2a6-4798-a815-17e0f08224a2'	System	03 Aug 2020 23:24:48
User entered 'None (1)'	System	03 Aug 2020 23:24:48

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:33', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '19f0d75d-f2a6-4798-a815-17e0f08224a2'	System	03 Aug 2020 23:24:48
User entered 'No (N)'	System	03 Aug 2020 23:24:48

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '19f0d75d-f2a6-4798-a815-17e0f08224a2'	System	03 Aug 2020 23:24:48
User entered 'No (N)'	System	03 Aug 2020 23:24:48

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:38', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '19f0d75d-f2a6-4798-a815-17e0f08224a2'	System	03 Aug 2020 23:24:48
User entered 'None (1)'	System	03 Aug 2020 23:24:48

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '19f0d75d-f2a6-4798-a815-17e0f08224a2'	System	03 Aug 2020 23:24:48
User entered '03 Aug 2020 19:24'	System	03 Aug 2020 23:24:48



US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 7'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '307237fb-6591-42b6-9c9c-380c8ffa8860'	System	05 Aug 2020 12:07:07
User entered 'None (1)'	System	05 Aug 2020 12:07:07

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '307237fb-6591-42b6-9c9c-380c8ffa8860'	System	05 Aug 2020 12:07:07
User entered 'No (N)'	System	05 Aug 2020 12:07:07

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:06:57', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '307237fb-6591-42b6-9c9c-380c8ffa8860'	System	05 Aug 2020 12:07:07
User entered 'No (N)'	System	05 Aug 2020 12:07:07

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '307237fb-6591-42b6-9c9c-380c8ffa8860'	System	05 Aug 2020 12:07:07
User entered 'None (1)'	System	05 Aug 2020 12:07:07

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '307237fb-6591-42b6-9c9c-380c8ffa8860'	System	05 Aug 2020 12:07:07
User entered '05 Aug 2020 08:07'	System	05 Aug 2020 12:07:07



**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:34', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:41', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:43', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'None (0)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered 'No (N)'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-29T10:49:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'efabb4c3-5532-45b9-9c86-a086d4fee775'	System	29 Jul 2020 14:49:56
User entered '29 Jul 2020 10:49'	System	29 Jul 2020 14:49:56

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Jul 2020 14:02'	System	12 Aug 2020 23:20:32
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 2'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:06', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:19', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:23', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'None (0)'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:29', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered 'No (N)'	System	31 Jul 2020 00:30:42



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-30T20:30:35', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '1151883a-7744-4711-91f1-f8a2247c8f4b'	System	31 Jul 2020 00:30:42
User entered '30 Jul 2020 20:30'	System	31 Jul 2020 00:30:42

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 3'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:16', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'None (0)'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:28', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered 'No (N)'	System	31 Jul 2020 17:19:39

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-07-31T13:19:33', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0aba93f-f4a2-432b-b8a5-c31ec4c0b921'	System	31 Jul 2020 17:19:39
User entered '31 Jul 2020 13:19'	System	31 Jul 2020 17:19:39

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 4'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:26', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:28', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'None (0)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:35', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered 'No (N)'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-01T18:41:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbfe5927-b03d-470e-9891-c7d239533a20'	System	01 Aug 2020 22:41:43
User entered '01 Aug 2020 18:41'	System	01 Aug 2020 22:41:43

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 5'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:40', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:43', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:21:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'None (0)'	System	02 Aug 2020 23:22:25



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:22:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered 'No (N)'	System	02 Aug 2020 23:22:25

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-02T19:22:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd32e571e-66b1-4022-bc89-ddcee5a6be3f'	System	02 Aug 2020 23:22:25
User entered '02 Aug 2020 19:22'	System	02 Aug 2020 23:22:25

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 6'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:55', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:24:58', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:01', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'None (0)'	System	03 Aug 2020 23:25:34

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:27', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered 'No (N)'	System	03 Aug 2020 23:25:34

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-03T19:25:31', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a2d22041-6cbf-43a2-b6af-4fc89639e2b0'	System	03 Aug 2020 23:25:34
User entered '03 Aug 2020 19:25'	System	03 Aug 2020 23:25:34

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 7'	System	29 Jul 2020 14:31:33



US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:15', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:20', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'None (0)'	System	05 Aug 2020 12:07:40

US3022063

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:33', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered 'No (N)'	System	05 Aug 2020 12:07:40

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-05T08:07:37', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2934fa5b-9b8b-4214-863f-e96b09f4e8f9'	System	05 Aug 2020 12:07:40
User entered '05 Aug 2020 08:07'	System	05 Aug 2020 12:07:40



**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 14:31:33

**US3022063**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:00:34
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Aug 2020 19:57:48

US3022063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Protocol deviation 'Safety call date of contact is greater than 10 days after visit 1 treatment date.' inactivated.	(b) (4), (b) (6)	10 Nov 2020 21:14:46
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:00:34
Protocol deviation created: Safety call date of contact is greater than 10 days after visit 1 treatment date. Class: Incl/Excl Criteria not met Code: Deviation.	(b) (4), (b) (6)	30 Sep 2020 13:59:54
User closed query ' Per CDM: Date of Safety Call Day 8 'Date of Contact or Contact Attempt' is reported grater then 10 days from Visit 1 Treatment Date on the Exposure Form. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 05:59:30
Query ' Per CDM: Date of Safety Call Day 8 'Date of Contact or Contact Attempt' is reported grater then 10 days from Visit 1 Treatment Date on the Exposure Form. Please review and reconcile ' answered with 'Date is correct. deviation recorded' (Site from DM).	Shanice Bennett (b) (4)	22 Aug 2020 01:48:12
User opened query ' Per CDM: Date of Safety Call Day 8 'Date of Contact or Contact Attempt' is reported grater then 10 days from Visit 1 Treatment Date on the Exposure Form. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 13:30:30
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) (6)	13 Aug 2020 13:30:05
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 'correct date' (Site from System).	Shanice Bennett (b) (4)	10 Aug 2020 19:58:00

US3022063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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	10 Aug 2020 19:57:48
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 19:57:48

US3022063

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:00:34
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	10 Aug 2020 19:57:48

**US3022063**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:00:34
User entered empty.	Shanice Bennett (b) (4)	10 Aug 2020 19:57:48

US3022063

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:01:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Aug 2020 19:57:53



**US3022063**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	10 Aug 2020 19:57:53

**US3022063**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:22
User entered 'Yes (Y)'	Morgan Deal (b) (4)	17 Aug 2020 23:24:04

**US3022063**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:22
User entered '14 Aug 2020'	Morgan Deal (b) (4)	17 Aug 2020 23:24:04

US3022063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:22
User entered 'Contact Made (CONTACT MADE)'	Morgan Deal (b) (4)	17 Aug 2020 23:24:04

US3022063

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:04:22
User entered empty.	Morgan Deal (b) (4) (b) (4)	17 Aug 2020 23:24:04

US3022063

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:36
User entered 'Yes (Y)'	Morgan Deal (b) (4)	17 Aug 2020 23:24:07

**US3022063**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	17 Aug 2020 23:24:07

**US3022063**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:36:19



**US3022063**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:55
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 18:36:19

US3022063

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 18:36:19

**US3022063**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:04:55
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:36:19

**US3022063**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:36:23

**US3022063**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	19 Aug 2020 18:36:23

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:17
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:03:38

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:17
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 14:03:38

US3022063

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

[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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:17
User entered 'Clinic (Clinic)'	Chevon Roberts (b) (4)	27 Aug 2020 14:03:38



**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'VISIT2'	System	27 Aug 2020 14:03:38

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Pre-Dose (PREDOSE)'	Chevon Roberts (b) (4) (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '07:59'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '27 Aug 2020 07:59'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '37.1' C	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39



US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered empty.	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '67'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'bpm'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '15'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'breaths/min'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '140'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '86'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39



US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Post-Dose (POSTDOSE)'	Chevon Roberts (b) (4) (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User closed query 'Per CDM: the treatment time on the Exposure CRF is 09:17. The Vital Signs Post Dose Time of Assessment is 09:44. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4)	20 Nov 2020 09:02:21
Query 'Per CDM: the treatment time on the Exposure CRF is 09:17. The Vital Signs Post Dose Time of Assessment is 09:44. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' answered with 'this time is correct' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 21:09:38
User opened query 'Per CDM: the treatment time on the Exposure CRF is 09:17. The Vital Signs Post Dose Time of Assessment is 09:44. Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:12:17
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 14:04:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Aug 2020 14:04:48
User entered '09:44' reason for change: Data Entry Error	Chevon Roberts (b) (4)	27 Aug 2020 14:04:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 14:04:39
User entered empty.	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '27 Aug 2020 09:44'	System	27 Aug 2020 14:04:48
User entered empty.	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '36.8' C	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered 'Oral (Oral)'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39



US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered empty.	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '61'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'bpm'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '16'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'breaths/min'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '136'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:34
User entered '80'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:39



US3022063

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'mmHg'	System	27 Aug 2020 14:04:39

US3022063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:44
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:56

US3022063

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:05:44
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 14:04:56

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered empty.	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

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 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered empty.	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18



US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered '09:17'	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:51:44**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '27 Aug 2020 09:17'	System	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4)	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:41
User entered 'ONCE'	System	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:51:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 13:43:18

US3022063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:34
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:05:14

US3022063

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:34
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	27 Aug 2020 14:05:14

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:06:34
User entered '08:08'	Chevon Roberts (b) (4)	27 Aug 2020 14:05:14



**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '27 Aug 2020 08:08'	System	27 Aug 2020 14:05:14

US3022063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:07:07
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 12:48:40
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		01 Sep 2020 12:48:40
User entered '27 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 12:48:40
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 12:48:06
User entered '28 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 12:48:06

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06

US3022063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:07
User entered '08:21' reason for change: Data Entry Error	Shanice Bennett (b) (4)	01 Sep 2020 12:48:40
User entered '09:42'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered '27 Aug 2020 08:21'	System	01 Sep 2020 12:48:40
User entered '28 Aug 2020 09:42'	System	01 Sep 2020 12:48:06

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06

US3022063

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:07
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06



**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:07
User entered empty.	Shanice Bennett (b) (4)	01 Sep 2020 12:48:06

**US3022063**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered empty.	System	01 Sep 2020 12:48:06

US3022063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:14
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	27 Aug 2020 14:05:22

US3022063

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	27 Aug 2020 14:05:22

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9a25f6ef-953e-417b-a7c7-7c907ec0b44a'	System	27 Aug 2020 13:48:47
User entered 'Yes (Y)'	System	27 Aug 2020 13:48:47

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9a25f6ef-953e-417b-a7c7-7c907ec0b44a'	System	27 Aug 2020 13:48:47
User entered '98.3'	System	27 Aug 2020 13:48:47

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9a25f6ef-953e-417b-a7c7-7c907ec0b44a'	System	27 Aug 2020 13:48:47
User entered 'No (N)'	System	27 Aug 2020 13:48:47



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:40', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9a25f6ef-953e-417b-a7c7-7c907ec0b44a'	System	27 Aug 2020 13:48:47
User entered '27 Aug 2020 09:48'	System	27 Aug 2020 13:48:47

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 09:37'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 12:07'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3fe36b3d-ed40-47a9-851f-31c3b1db4a03'	System	28 Aug 2020 00:07:23
User entered 'Yes (Y)'	System	28 Aug 2020 00:07:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:06', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3fe36b3d-ed40-47a9-851f-31c3b1db4a03'	System	28 Aug 2020 00:07:23
User entered '98.3'	System	28 Aug 2020 00:07:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3fe36b3d-ed40-47a9-851f-31c3b1db4a03'	System	28 Aug 2020 00:07:23
User entered 'No (N)'	System	28 Aug 2020 00:07:23

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:17', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3fe36b3d-ed40-47a9-851f-31c3b1db4a03'	System	28 Aug 2020 00:07:23
User entered '27 Aug 2020 20:07'	System	28 Aug 2020 00:07:23



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 13:02'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 2'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5488160c-4aee-42a6-abde-4f9ae75d25f8'	System	29 Aug 2020 02:15:29
User entered 'Yes (Y)'	System	29 Aug 2020 02:15:29

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:14', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5488160c-4aee-42a6-abde-4f9ae75d25f8'	System	29 Aug 2020 02:15:29
User entered '97.9'	System	29 Aug 2020 02:15:29

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:19', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5488160c-4aee-42a6-abde-4f9ae75d25f8'	System	29 Aug 2020 02:15:29
User entered 'No (N)'	System	29 Aug 2020 02:15:29

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5488160c-4aee-42a6-abde-4f9ae75d25f8'	System	29 Aug 2020 02:15:29
User entered '28 Aug 2020 22:15'	System	29 Aug 2020 02:15:29

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 3'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26237875-427b-4881-864f-d00899dcdd28'	System	29 Aug 2020 21:56:45
User entered 'Yes (Y)'	System	29 Aug 2020 21:56:45

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:34', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26237875-427b-4881-864f-d00899dcdd28'	System	29 Aug 2020 21:56:45
User entered '97.9'	System	29 Aug 2020 21:56:45

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26237875-427b-4881-864f-d00899dcdd28'	System	29 Aug 2020 21:56:45
User entered 'No (N)'	System	29 Aug 2020 21:56:45

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26237875-427b-4881-864f-d00899dcdd28'	System	29 Aug 2020 21:56:45
User entered '29 Aug 2020 17:56'	System	29 Aug 2020 21:56:45

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 4'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:36:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f41535f0-6086-4dfa-b3c3-8ff8899cc847'	System	30 Aug 2020 23:37:11
User entered 'Yes (Y)'	System	30 Aug 2020 23:37:11

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:36:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f41535f0-6086-4dfa-b3c3-8ff8899cc847'	System	30 Aug 2020 23:37:11
User entered '97.3'	System	30 Aug 2020 23:37:11

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:02', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f41535f0-6086-4dfa-b3c3-8ff8899cc847'	System	30 Aug 2020 23:37:11
User entered 'No (N)'	System	30 Aug 2020 23:37:11

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f41535f0-6086-4dfa-b3c3-8ff8899cc847'	System	30 Aug 2020 23:37:11
User entered '30 Aug 2020 19:37'	System	30 Aug 2020 23:37:11

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 5'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:04', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ac01c580-ab47-441c-a8aa-98b8f6b2d3d4'	System	01 Sep 2020 00:42:23
User entered 'Yes (Y)'	System	01 Sep 2020 00:42:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ac01c580-ab47-441c-a8aa-98b8f6b2d3d4'	System	01 Sep 2020 00:42:23
User entered '98.1'	System	01 Sep 2020 00:42:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:15', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ac01c580-ab47-441c-a8aa-98b8f6b2d3d4'	System	01 Sep 2020 00:42:23
User entered 'No (N)'	System	01 Sep 2020 00:42:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ac01c580-ab47-441c-a8aa-98b8f6b2d3d4'	System	01 Sep 2020 00:42:23
User entered '31 Aug 2020 20:42'	System	01 Sep 2020 00:42:23

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 6'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 7'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:08', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d5fe79d-59da-4a50-b611-5a7d264ac091'	System	03 Sep 2020 01:45:28
User entered 'Yes (Y)'	System	03 Sep 2020 01:45:28

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:15', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d5fe79d-59da-4a50-b611-5a7d264ac091'	System	03 Sep 2020 01:45:28
User entered '97.7'	System	03 Sep 2020 01:45:28

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:19', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d5fe79d-59da-4a50-b611-5a7d264ac091'	System	03 Sep 2020 01:45:28
User entered 'No (N)'	System	03 Sep 2020 01:45:28

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '2d5fe79d-59da-4a50-b611-5a7d264ac091'	System	03 Sep 2020 01:45:28
User entered '02 Sep 2020 21:45'	System	03 Sep 2020 01:45:28

US3022063

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:46', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '86603033-bb01-41da-a1c2-6ed33487b017'	System	27 Aug 2020 13:49:06
User entered 'None (1)'	System	27 Aug 2020 13:49:06



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:49', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '86603033-bb01-41da-a1c2-6ed33487b017'	System	27 Aug 2020 13:49:06
User entered 'No (N)'	System	27 Aug 2020 13:49:06

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '86603033-bb01-41da-a1c2-6ed33487b017'	System	27 Aug 2020 13:49:06
User entered 'No (N)'	System	27 Aug 2020 13:49:06

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '86603033-bb01-41da-a1c2-6ed33487b017'	System	27 Aug 2020 13:49:06
User entered 'None (1)'	System	27 Aug 2020 13:49:06

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:48:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '86603033-bb01-41da-a1c2-6ed33487b017'	System	27 Aug 2020 13:49:06
User entered '27 Aug 2020 09:48'	System	27 Aug 2020 13:49:06

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 09:37'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 12:07'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:23', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e4d00f5-3081-4d72-9b6f-d23f72823315'	System	28 Aug 2020 00:07:51
User entered 'None (1)'	System	28 Aug 2020 00:07:51



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:28', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e4d00f5-3081-4d72-9b6f-d23f72823315'	System	28 Aug 2020 00:07:51
User entered 'No (N)'	System	28 Aug 2020 00:07:51

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:34', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e4d00f5-3081-4d72-9b6f-d23f72823315'	System	28 Aug 2020 00:07:51
User entered 'No (N)'	System	28 Aug 2020 00:07:51

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e4d00f5-3081-4d72-9b6f-d23f72823315'	System	28 Aug 2020 00:07:51
User entered 'None (1)'	System	28 Aug 2020 00:07:51

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:47', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e4d00f5-3081-4d72-9b6f-d23f72823315'	System	28 Aug 2020 00:07:51
User entered '27 Aug 2020 20:07'	System	28 Aug 2020 00:07:51

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 13:02'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 2'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:27', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f6f46f1b-02fe-4d7c-b399-c3d63b77796d'	System	29 Aug 2020 02:15:44
User entered 'None (1)'	System	29 Aug 2020 02:15:44



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:29', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f6f46f1b-02fe-4d7c-b399-c3d63b77796d'	System	29 Aug 2020 02:15:44
User entered 'No (N)'	System	29 Aug 2020 02:15:44

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f6f46f1b-02fe-4d7c-b399-c3d63b77796d'	System	29 Aug 2020 02:15:44
User entered 'No (N)'	System	29 Aug 2020 02:15:44

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:36', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f6f46f1b-02fe-4d7c-b399-c3d63b77796d'	System	29 Aug 2020 02:15:44
User entered 'None (1)'	System	29 Aug 2020 02:15:44

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:39', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'f6f46f1b-02fe-4d7c-b399-c3d63b77796d'	System	29 Aug 2020 02:15:44
User entered '28 Aug 2020 22:15'	System	29 Aug 2020 02:15:44

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 3'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'cee1c717-42c8-4c5d-b89c-b6b614c42db4'	System	29 Aug 2020 21:57:02
User entered 'None (1)'	System	29 Aug 2020 21:57:02



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:49', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'cee1c717-42c8-4c5d-b89c-b6b614c42db4'	System	29 Aug 2020 21:57:02
User entered 'No (N)'	System	29 Aug 2020 21:57:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'cee1c717-42c8-4c5d-b89c-b6b614c42db4'	System	29 Aug 2020 21:57:02
User entered 'No (N)'	System	29 Aug 2020 21:57:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:57', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'cee1c717-42c8-4c5d-b89c-b6b614c42db4'	System	29 Aug 2020 21:57:02
User entered 'None (1)'	System	29 Aug 2020 21:57:02

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:56:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'cee1c717-42c8-4c5d-b89c-b6b614c42db4'	System	29 Aug 2020 21:57:02
User entered '29 Aug 2020 17:56'	System	29 Aug 2020 21:57:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 4'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:11', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e16f9ee0-7c6f-4fba-8c5d-07416bbb8265'	System	30 Aug 2020 23:37:27
User entered 'None (1)'	System	30 Aug 2020 23:37:27



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e16f9ee0-7c6f-4fba-8c5d-07416bbb8265'	System	30 Aug 2020 23:37:27
User entered 'No (N)'	System	30 Aug 2020 23:37:27

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:16', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e16f9ee0-7c6f-4fba-8c5d-07416bbb8265'	System	30 Aug 2020 23:37:27
User entered 'No (N)'	System	30 Aug 2020 23:37:27

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:19', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e16f9ee0-7c6f-4fba-8c5d-07416bbb8265'	System	30 Aug 2020 23:37:27
User entered 'None (1)'	System	30 Aug 2020 23:37:27

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e16f9ee0-7c6f-4fba-8c5d-07416bbb8265'	System	30 Aug 2020 23:37:27
User entered '30 Aug 2020 19:37'	System	30 Aug 2020 23:37:27

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 5'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6d4c4713-c038-4448-b191-e8adf4286ac3'	System	01 Sep 2020 00:42:36
User entered 'None (1)'	System	01 Sep 2020 00:42:36



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6d4c4713-c038-4448-b191-e8adf4286ac3'	System	01 Sep 2020 00:42:36
User entered 'No (N)'	System	01 Sep 2020 00:42:36

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:26', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6d4c4713-c038-4448-b191-e8adf4286ac3'	System	01 Sep 2020 00:42:36
User entered 'No (N)'	System	01 Sep 2020 00:42:36

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:28', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6d4c4713-c038-4448-b191-e8adf4286ac3'	System	01 Sep 2020 00:42:36
User entered 'None (1)'	System	01 Sep 2020 00:42:36

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6d4c4713-c038-4448-b191-e8adf4286ac3'	System	01 Sep 2020 00:42:36
User entered '31 Aug 2020 20:42'	System	01 Sep 2020 00:42:36

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 6'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 7'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:42', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ed6bc6d-fafb-4dc8-b35b-29fbd34bac47'	System	03 Sep 2020 01:46:01
User entered 'None (1)'	System	03 Sep 2020 01:46:01

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ed6bc6d-fafb-4dc8-b35b-29fbd34bac47'	System	03 Sep 2020 01:46:01
User entered 'No (N)'	System	03 Sep 2020 01:46:01

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ed6bc6d-fafb-4dc8-b35b-29fbd34bac47'	System	03 Sep 2020 01:46:01
User entered 'No (N)'	System	03 Sep 2020 01:46:01

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:50', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ed6bc6d-fafb-4dc8-b35b-29fbd34bac47'	System	03 Sep 2020 01:46:01
User entered 'None (1)'	System	03 Sep 2020 01:46:01

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:45:56', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ed6bc6d-fafb-4dc8-b35b-29fbd34bac47'	System	03 Sep 2020 01:46:01
User entered '02 Sep 2020 21:45'	System	03 Sep 2020 01:46:01

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:05', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:12', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:16', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'None (0)'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:24', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered 'No (N)'	System	27 Aug 2020 13:49:39



**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T09:49:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7f4bea11-f056-4157-ad5a-2c3e0184f6bf'	System	27 Aug 2020 13:49:39
User entered '27 Aug 2020 09:49'	System	27 Aug 2020 13:49:39

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 09:37'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 12:07'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:55', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:07:58', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:01', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:05', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'None (0)'	System	28 Aug 2020 00:08:20

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:11', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered 'No (N)'	System	28 Aug 2020 00:08:20

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-27T20:08:14', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9da6745b-e0f5-485a-995a-de07237ca640'	System	28 Aug 2020 00:08:20
User entered '27 Aug 2020 20:08'	System	28 Aug 2020 00:08:20

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '27 Aug 2020 13:02'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 2'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:43', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:53', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'None (0)'	System	29 Aug 2020 02:16:05

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:15:57', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered 'No (N)'	System	29 Aug 2020 02:16:05

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-28T22:16:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '57eb8b0b-529b-4f4c-aea5-14d01fda39c0'	System	29 Aug 2020 02:16:05
User entered '28 Aug 2020 22:16'	System	29 Aug 2020 02:16:05

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:51:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 3'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:05', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:11', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'None (0)'	System	29 Aug 2020 21:57:21



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:14', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered 'No (N)'	System	29 Aug 2020 21:57:21

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-29T17:57:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '84138ec1-63f8-4292-87b3-bc896b976d8d'	System	29 Aug 2020 21:57:21
User entered '29 Aug 2020 17:57'	System	29 Aug 2020 21:57:21

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 4'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:26', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:28', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:30', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:34', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:37', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'None (0)'	System	30 Aug 2020 23:37:49

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:42', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered 'No (N)'	System	30 Aug 2020 23:37:49

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-30T19:37:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '80ed9f29-3675-4482-a83e-097d6002d440'	System	30 Aug 2020 23:37:49
User entered '30 Aug 2020 19:37'	System	30 Aug 2020 23:37:49

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 5'	System	27 Aug 2020 13:43:18



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:42', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:46', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:50', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'None (0)'	System	01 Sep 2020 00:43:00

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered 'No (N)'	System	01 Sep 2020 00:43:00

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-08-31T20:42:56', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '42400f49-1581-4649-96ca-cf667250f424'	System	01 Sep 2020 00:43:00
User entered '31 Aug 2020 20:42'	System	01 Sep 2020 00:43:00



**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 6'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:51:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 13:43:18

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	27 Aug 2020 13:43:18
User entered 'Day 7'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:06', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31



US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:14', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'None (0)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:23', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered 'No (N)'	System	03 Sep 2020 01:46:31

US3022063

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:51:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-09-02T21:46:26', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'd798ef5a-94e8-44ff-9818-f609188847f3'	System	03 Sep 2020 01:46:31
User entered '02 Sep 2020 21:46'	System	03 Sep 2020 01:46:31

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 13:43:18

**US3022063**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:51:44**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 13:43:18



**US3022063**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:26
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:29

**US3022063**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:26
User entered '03 Sep 2020'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:29

US3022063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:26
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:29

US3022063

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:26
User entered empty.	Shanice Bennett (b) (4)	17 Sep 2020 18:42:29

**US3022063**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:41
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:33

**US3022063**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	17 Sep 2020 18:42:33

**US3022063**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:58
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:53

**US3022063**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:58
User entered '11 Sep 2020'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:53



US3022063

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:58
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:53

**US3022063**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:07:58
User entered empty.	Shanice Bennett (b) (4)	17 Sep 2020 18:42:53

**US3022063**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:05
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:42:58

US3022063

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	17 Sep 2020 18:42:58

**US3022063**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:16
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:43:10

**US3022063**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:16
User entered '17 Sep 2020'	Shanice Bennett (b) (4)	17 Sep 2020 18:43:10

**US3022063**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:16
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	17 Sep 2020 18:43:10

US3022063

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:16
User entered empty.	Shanice Bennett (b) (4)	17 Sep 2020 18:43:10



US3022063

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 14:08:22
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Sep 2020 18:43:15

**US3022063**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	17 Sep 2020 18:43:15

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:35
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:51:07

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:36
	(b) (4), (b) (6)	
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 12:51:07

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[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 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:38
	(b) (4), (b) (6)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 12:51:07

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered 'VISIT3'	System	01 Oct 2020 12:51:07

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:45
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:46
	(b) (4), (b) (6)	
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 12:51:46



**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:48
	(b) (4), (b) (6)	
User entered '08:10'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered '01 Oct 2020 08:10'	System	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:49
	(b) (4), (b) (6)	
User entered '36.8' C	(b) (4), (b) (6)	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:51
	(b) (4), (b) (6)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:55
	(b) (4), (b) (6)	
User entered '72'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered 'bpm'	System	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:57
	(b) (4), (b) (6)	
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 12:51:46



US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered 'breaths/min'	System	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:49:59
	(b) (4), (b) (6)	
User entered '118'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered 'mmHg'	System	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:01
	(b) (4), (b) (6)	
User entered '82'	(b) (4), (b) (6)	01 Oct 2020 12:51:46

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered 'mmHg'	System	01 Oct 2020 12:51:46

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41

US3022063

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41

US3022063

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:17
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:52:00



**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:51:44**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:19
	(b) (4), (b) (6)	
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 12:52:00

US3022063

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:28
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:52:21

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:29
	(b) (4), (b) (6)	
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 12:52:21

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:50:31
	(b) (4), (b) (6)	
User entered '08:26'	(b) (4), (b) (6)	01 Oct 2020 12:52:21

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:41
User entered '01 Oct 2020 08:26'	System	01 Oct 2020 12:52:21

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	26 Jan 2021 20:51:08
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 12:52:34

**US3022063**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	01 Oct 2020 12:52:34

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 64'	System	29 Jul 2020 14:31:33



US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-02T17:45:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7d1b433b-e708-4487-9183-63b8156eb4e1'	System	02 Oct 2020 21:45:27
User entered 'No (N)'	System	02 Oct 2020 21:45:27

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-02T17:45:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7d1b433b-e708-4487-9183-63b8156eb4e1'	System	02 Oct 2020 21:45:27
User entered 'No (N)'	System	02 Oct 2020 21:45:27

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-02T17:45:16', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7d1b433b-e708-4487-9183-63b8156eb4e1'	System	02 Oct 2020 21:45:27
User entered '02 Oct 2020 17:45:16'	System	02 Oct 2020 21:45:27

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 71'	System	29 Jul 2020 14:31:33

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-05T18:51:47', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '09a12406-ea3f-43e8-b80f-8151f738cc94'	System	05 Oct 2020 22:52:03
User entered 'No (N)'	System	05 Oct 2020 22:52:03

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-05T18:51:50', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '09a12406-ea3f-43e8-b80f-8151f738cc94'	System	05 Oct 2020 22:52:03
User entered 'No (N)'	System	05 Oct 2020 22:52:03



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-05T18:51:53', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '09a12406-ea3f-43e8-b80f-8151f738cc94'	System	05 Oct 2020 22:52:03
User entered '05 Oct 2020 18:51:53'	System	05 Oct 2020 22:52:03

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 78'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 92'	System	29 Jul 2020 14:31:33



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-27T17:38:29', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '69303915-6758-4f18-9dab-8751e45d9973'	System	27 Oct 2020 21:38:44
User entered 'No (N)'	System	27 Oct 2020 21:38:44

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-27T17:38:34', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '69303915-6758-4f18-9dab-8751e45d9973'	System	27 Oct 2020 21:38:44
User entered 'No (N)'	System	27 Oct 2020 21:38:44

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-10-27T17:38:40', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '69303915-6758-4f18-9dab-8751e45d9973'	System	27 Oct 2020 21:38:44
User entered '27 Oct 2020 17:38:40'	System	27 Oct 2020 21:38:44

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 99'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

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

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 14:31:33



**US3022063**

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

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**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:39:28
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 106'	System	29 Jul 2020 14:31:33

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-09T04:14:37', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5a00aedb-ed28-4097-8695-9e5077b405c2'	System	09 Nov 2020 09:15:06
User entered 'No (N)'	System	09 Nov 2020 09:15:06

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-09T04:14:41', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5a00aedb-ed28-4097-8695-9e5077b405c2'	System	09 Nov 2020 09:15:06
User entered 'No (N)'	System	09 Nov 2020 09:15:06

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-09T04:14:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5a00aedb-ed28-4097-8695-9e5077b405c2'	System	09 Nov 2020 09:15:06
User entered '09 Nov 2020 04:14:59'	System	09 Nov 2020 09:15:06

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered 'Day 113'	System	29 Jul 2020 14:31:33



US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-16T20:40:59', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3a111897-cd05-4441-ab8a-efd638d16310'	System	17 Nov 2020 01:41:17
User entered 'No (N)'	System	17 Nov 2020 01:41:17

US3022063

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:51:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-16T20:41:03', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3a111897-cd05-4441-ab8a-efd638d16310'	System	17 Nov 2020 01:41:17
User entered 'No (N)'	System	17 Nov 2020 01:41:17

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-16T20:41:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3a111897-cd05-4441-ab8a-efd638d16310'	System	17 Nov 2020 01:41:17
User entered '16 Nov 2020 20:41:10'	System	17 Nov 2020 01:41:17

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:36:02
Data entry locked.	System	29 Jul 2020 14:31:33
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 14:31:33

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2020-11-21T08:26:44', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '20fcf803-4f10-4cbc-8477-2e85e911489c'	System	21 Nov 2020 13:27:00
User entered 'No (N)'	System	21 Nov 2020 13:27:00

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2020-11-21T08:26:47', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '20fcf803-4f10-4cbc-8477-2e85e911489c'	System	21 Nov 2020 13:27:00
User entered 'No (N)'	System	21 Nov 2020 13:27:00



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-11-21T08:26:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '20fcf803-4f10-4cbc-8477-2e85e911489c'	System	21 Nov 2020 13:27:00
User entered '21 Nov 2020 08:26:52'	System	21 Nov 2020 13:27:00

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2020-12-15T14:15:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6451ce3e-0ed2-4a99-90cb-3eea351812df'	System	15 Dec 2020 19:15:51
User entered 'No (N)'	System	15 Dec 2020 19:15:51

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2020-12-15T14:15:25', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6451ce3e-0ed2-4a99-90cb-3eea351812df'	System	15 Dec 2020 19:15:51
User entered 'No (N)'	System	15 Dec 2020 19:15:51

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-12-15T14:15:47', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '6451ce3e-0ed2-4a99-90cb-3eea351812df' User entered '15 Dec 2020 14:15:47'	System	15 Dec 2020 19:15:51
	System	15 Dec 2020 19:15:51

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2020-12-27T09:45:21', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0d638da8-300b-447b-9aad-43da68621cc1'	System	27 Dec 2020 14:45:39
User entered 'No (N)'	System	27 Dec 2020 14:45:39

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2020-12-27T09:45:18', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0d638da8-300b-447b-9aad-43da68621cc1'	System	27 Dec 2020 14:45:39
User entered 'No (N)'	System	27 Dec 2020 14:45:39

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2020-12-27T09:45:32', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '0d638da8-300b-447b-9aad-43da68621cc1'	System	27 Dec 2020 14:45:39
User entered '27 Dec 2020 09:45:32'	System	27 Dec 2020 14:45:39

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:39:28



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-01-04T14:46:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3d0a944a-1d2c-46e2-84a8-557a2d662f05'	System	04 Jan 2021 19:46:59
User entered 'No (N)'	System	04 Jan 2021 19:46:59

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-01-04T14:46:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3d0a944a-1d2c-46e2-84a8-557a2d662f05'	System	04 Jan 2021 19:46:59
User entered 'No (N)'	System	04 Jan 2021 19:46:59

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-01-04T14:46:54', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3d0a944a-1d2c-46e2-84a8-557a2d662f05'	System	04 Jan 2021 19:46:59
User entered '04 Jan 2021 14:46:54'	System	04 Jan 2021 19:46:59

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:39:28

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-01-11T05:19:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a5a6510a-1c0a-4b37-b899-c8760dcee2e5'	System	11 Jan 2021 10:20:01
User entered 'No (N)'	System	11 Jan 2021 10:20:01



**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-01-11T05:19:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a5a6510a-1c0a-4b37-b899-c8760dcee2e5'	System	11 Jan 2021 10:20:01
User entered 'No (N)'	System	11 Jan 2021 10:20:01

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-01-11T05:19:56', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'a5a6510a-1c0a-4b37-b899-c8760dcee2e5'	System	11 Jan 2021 10:20:01
User entered '11 Jan 2021 05:19:56'	System	11 Jan 2021 10:20:01

**US3022063**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-01-16T20:08:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0a778ac-17bf-4ede-90e1-1c86f1b9f96b'	System	17 Jan 2021 01:09:02
User entered 'No (N)'	System	17 Jan 2021 01:09:02

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-01-16T20:08:52', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0a778ac-17bf-4ede-90e1-1c86f1b9f96b'	System	17 Jan 2021 01:09:02
User entered 'No (N)'	System	17 Jan 2021 01:09:02

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-01-16T20:08:56', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'b0a778ac-17bf-4ede-90e1-1c86f1b9f96b'	System	17 Jan 2021 01:09:02
User entered '16 Jan 2021 20:08:56'	System	17 Jan 2021 01:09:02



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-01-25T07:50:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ccc64e3-7171-44f4-9ee4-bb212fb57832'	System	25 Jan 2021 12:50:19
User entered 'No (N)'	System	25 Jan 2021 12:50:19

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-01-25T07:50:09', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ccc64e3-7171-44f4-9ee4-bb212fb57832'	System	25 Jan 2021 12:50:19
User entered 'No (N)'	System	25 Jan 2021 12:50:19

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-01-25T07:50:13', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '3ccc64e3-7171-44f4-9ee4-bb212fb57832'	System	25 Jan 2021 12:50:19
User entered '25 Jan 2021 07:50:13'	System	25 Jan 2021 12:50:19

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-02-02T13:13:05', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'dd3baba2-92d3-4281-86e2-f6b8091c842d'	System	02 Feb 2021 18:13:26
User entered 'No (N)'	System	02 Feb 2021 18:13:26

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-02-02T13:13:07', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'dd3baba2-92d3-4281-86e2-f6b8091c842d'	System	02 Feb 2021 18:13:26
User entered 'No (N)'	System	02 Feb 2021 18:13:26

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-02-02T13:13:10', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'dd3baba2-92d3-4281-86e2-f6b8091c842d'	System	02 Feb 2021 18:13:26
User entered '02 Feb 2021 13:13:10'	System	02 Feb 2021 18:13:26

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-02-07T00:38:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9271a38c-b396-4b13-bed2-e233b7d82db1'	System	07 Feb 2021 05:39:06
User entered 'No (N)'	System	07 Feb 2021 05:39:06



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-02-07T00:38:53', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9271a38c-b396-4b13-bed2-e233b7d82db1'	System	07 Feb 2021 05:39:06
User entered 'No (N)'	System	07 Feb 2021 05:39:06

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-02-07T00:39:01', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '9271a38c-b396-4b13-bed2-e233b7d82db1'	System	07 Feb 2021 05:39:06
User entered '07 Feb 2021 00:39:01'	System	07 Feb 2021 05:39:06

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-02-15T10:05:45', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7ae2fd38-9172-406a-a032-89eb87a101c0'	System	15 Feb 2021 15:05:59
User entered 'No (N)'	System	15 Feb 2021 15:05:59

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-02-15T10:05:48', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7ae2fd38-9172-406a-a032-89eb87a101c0'	System	15 Feb 2021 15:05:59
User entered 'No (N)'	System	15 Feb 2021 15:05:59

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-02-15T10:05:51', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '7ae2fd38-9172-406a-a032-89eb87a101c0'	System	15 Feb 2021 15:05:59
User entered '15 Feb 2021 10:05:51'	System	15 Feb 2021 15:05:59



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-02-20T08:41:19', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ccee81d-94a0-4e21-968c-75a5b058cccb'	System	20 Feb 2021 13:41:30
User entered 'No (N)'	System	20 Feb 2021 13:41:30

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-02-20T08:41:22', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ccee81d-94a0-4e21-968c-75a5b058cccb'	System	20 Feb 2021 13:41:30
User entered 'No (N)'	System	20 Feb 2021 13:41:30

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-02-20T08:41:27', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'ccee81d-94a0-4e21-968c-75a5b058cccb' User entered '20 Feb 2021 08:41:27'	System	20 Feb 2021 13:41:30

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-02-26T13:29:43-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbb6ef0c-1bb1-4b26-8f82-6638014cada1' User entered 'No (N)'	System	26 Feb 2021 18:30:04

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-02-26T13:29:52-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbb6ef0c-1bb1-4b26-8f82-6638014cada1'	System	26 Feb 2021 18:30:04
User entered 'No (N)'	System	26 Feb 2021 18:30:04

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-02-26T13:29:56-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'fbb6ef0c-1bb1-4b26-8f82-6638014cada1'	System	26 Feb 2021 18:30:04
User entered '26 Feb 2021 13:29:56'	System	26 Feb 2021 18:30:04

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-03-06T05:57:51-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c985ee6d-2c0e-4a37-968c-5849814da501'	System	06 Mar 2021 10:58:04
User entered 'No (N)'	System	06 Mar 2021 10:58:04



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-03-06T05:57:55-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c985ee6d-2c0e-4a37-968c-5849814da501'	System	06 Mar 2021 10:58:04
User entered 'No (N)'	System	06 Mar 2021 10:58:04

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-06T05:58:00-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'c985ee6d-2c0e-4a37-968c-5849814da501'	System	06 Mar 2021 10:58:04
User entered '06 Mar 2021 05:58:00'	System	06 Mar 2021 10:58:04

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-03-12T12:02:34-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26df40f7-f02e-4912-a52a-46dfb24ff4a3'	System	12 Mar 2021 17:05:39
User entered 'No (N)'	System	12 Mar 2021 17:05:39

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-03-12T12:02:36-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26df40f7-f02e-4912-a52a-46dfb24ff4a3'	System	12 Mar 2021 17:05:39
User entered 'No (N)'	System	12 Mar 2021 17:05:39

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-12T12:02:40-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '26df40f7-f02e-4912-a52a-46dfb24ff4a3'	System	12 Mar 2021 17:05:39
User entered '12 Mar 2021 12:02:40'	System	12 Mar 2021 17:05:39



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-03-19T20:53:34-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '05a3d950-248f-477d-9aff-5d4bd4593137'	System	20 Mar 2021 00:53:50
User entered 'No (N)'	System	20 Mar 2021 00:53:50

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-03-19T20:53:41-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '05a3d950-248f-477d-9aff-5d4bd4593137'	System	20 Mar 2021 00:53:50
User entered 'No (N)'	System	20 Mar 2021 00:53:50

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-19T20:53:46-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '05a3d950-248f-477d-9aff-5d4bd4593137'	System	20 Mar 2021 00:53:50
User entered '19 Mar 2021 20:53:46'	System	20 Mar 2021 00:53:50

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[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 (736dc5a1588510d9)', Time: '2021-03-27T16:10:06-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e707c78b-848b-4706-9580-c7367d28e507'	System	27 Mar 2021 20:10:18
User entered 'No (N)'	System	27 Mar 2021 20:10:18

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

Have you been exposed to someone with 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 (736dc5a1588510d9)', Time: '2021-03-27T16:10:08-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e707c78b-848b-4706-9580-c7367d28e507'	System	27 Mar 2021 20:10:18
User entered 'No (N)'	System	27 Mar 2021 20:10:18

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-27T16:10:11-04:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: 'e707c78b-848b-4706-9580-c7367d28e507'	System	27 Mar 2021 20:10:18
User entered '27 Mar 2021 16:10:11'	System	27 Mar 2021 20:10:18

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:39:28

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:39:28



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:39:28



**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:39:28

**US3022063**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:51:44**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:39:28
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:39:28

US3022063

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:51:44**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-01T07:11:22-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e15419c-6fd5-4ad8-861e-386ce11517af'	System	01 Mar 2021 12:11:40
User entered 'No (N)'	System	01 Mar 2021 12:11:40

**US3022063**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:38:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (736dc5a1588510d9)', Time: '2021-03-01T07:11:36-05:00', User OID: 'PatientReportedOutcome (US3022063)', ODM File OID: '5e15419c-6fd5-4ad8-861e-386ce11517af'	System	01 Mar 2021 12:11:40
User entered '01 Mar 2021 07:11:36'	System	01 Mar 2021 12:11:40

US3022063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:10:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:17:26

US3022063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:10:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:17:26

US3022063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:10:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 16:17:26



US3022063

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:10:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:17:26

US3022063

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:10:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:17:31

**US3022063**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:55:37
User entered 'I'	System	20 Oct 2020 16:17:31

**US3022063**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 13:23:48

US3022063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '23 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 13:23:48

**US3022063**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:51:44**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Dec 2020 13:23:48

US3022063

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 13:23:48

US3022063

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:15:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 13:23:59



**US3022063**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
User entered 'I'	System	07 Dec 2020 13:23:59

US3022063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 13:30:14

US3022063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '28 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 13:30:14

US3022063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 13:30:14

US3022063

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 13:30:14

US3022063

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:16:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 13:30:19

**US3022063**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
User entered 'I'	System	29 Dec 2020 13:30:19

US3022063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	21 Jan 2021 17:49:03



US3022063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '21 Jan 2021'	(b) (4) Morgan Deal (b) (4) (b) (4)	21 Jan 2021 17:49:03

US3022063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Deal (b) (4)	21 Jan 2021 17:49:03
	(b) (4)	

US3022063

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered empty.	(b) (4)	
	Morgan Deal (b) (4)	21 Jan 2021 17:49:03
	(b) (4)	

US3022063

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:11
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	21 Jan 2021 17:49:09
	(b) (4)	

**US3022063**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:55
User entered 'I'	System	21 Jan 2021 17:49:09

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 13:27:18

US3022063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 13:27:18

US3022063

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

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 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:17:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Feb 2021 13:27:18



**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered 'VISIT4'	System	11 Feb 2021 13:27:18

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered 'No (N)'	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:48:01
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:20:29

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:48:01
User entered empty.	Chevon Roberts (b) (4) (b) (4)	30 Mar 2021 16:20:29

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered empty.	System	30 Mar 2021 16:20:29

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	



**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered empty.	System	30 Mar 2021 16:20:29

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered empty.	System	30 Mar 2021 16:20:29

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered empty.	System	30 Mar 2021 16:20:29

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:48:01
	(b) (4), (b) (6)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:29
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered empty.	System	30 Mar 2021 16:20:29



US3022063

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:51:44

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:51:44**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36

US3022063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 13:27:48

US3022063

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:51:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:07
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 13:27:48

US3022063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:17
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:55
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	03 Mar 2021 15:58:46
	(b) (4)	

US3022063

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:17
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:55
	(b) (4)	
User entered '11 Feb 2021'	Chevon Roberts (b) (4)	03 Mar 2021 15:58:46
	(b) (4)	

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:17
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:55
	(b) (4)	
User entered '08:17'	Chevon Roberts (b) (4)	03 Mar 2021 15:58:46
	(b) (4)	

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered '11 Feb 2021 08:17'	System	03 Mar 2021 15:58:46



US3022063

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:18:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 13:28:00

**US3022063**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:36
User entered 'I'	System	11 Feb 2021 13:28:00

US3022063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:02
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:29
	(b) (4)	
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:43:33
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:42:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:42:42

US3022063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:02
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:29
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 17:42:42

US3022063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:02
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 17:43:33
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:42:42

US3022063

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:51:44

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:02
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:29
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 17:42:42

US3022063

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:51:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:12
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:01:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:43:49

**US3022063**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:51:44**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User entered 'I'	System	25 Mar 2021 17:43:49



US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:33:43

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '13 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:33:43

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:51:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:19:44
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 14:33:43

**US3022063**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:51:44**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 14:33:43

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '13 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

**US3022063**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:51:44**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:53:07
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 13:02:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:43:53

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:38
DataPoint Verified.	(b) (4)	07 Apr 2021 12:53:05
	(b) (4), (b) (6)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	29 Mar 2021 13:02:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:43:53



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '13 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 14:34:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:34:03

**US3022063**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:51:44**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User entered '1'	System	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:51:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User entered empty.	System	20 Jan 2021 14:34:26
User entered 'I'	System	20 Jan 2021 14:34:03

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:34:37



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '13 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:34:37

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:51:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:20:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '08:27'	(b) (4), (b) (6)	20 Jan 2021 14:34:37

**US3022063**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:51:44**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:06
User entered '13 Jan 2021 08:27'	System	20 Jan 2021 14:34:37

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:05
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:21:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:34:46

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:05
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:21:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '13 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:34:46

US3022063

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:51:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:05
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:21:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '08:35'	(b) (4), (b) (6)	20 Jan 2021 14:34:46

**US3022063**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:51:44**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:30:05
User entered '13 Jan 2021 08:35'	System	20 Jan 2021 14:34:46

US3022063

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:51:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:24
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:24:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	20 Apr 2021 19:31:17
DataPoint Un-verified.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:12
User entered 'No (N)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	20 Apr 2021 19:31:12
User closed query 'Please update to yes. Subject has SAE reported' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:54:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:54:32
Query 'Please update to yes. Subject has SAE reported' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:03:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 21:03:22
User opened query 'Please update to yes. Subject has SAE reported' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 12:57:31
DataPoint Un-verified.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:51
Signature has been broken.	Chevon Roberts (b) (4)	30 Mar 2021 16:20:51
User entered 'No (N)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	30 Mar 2021 16:20:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:15:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	13 Jan 2021 18:07:41

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:51:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Jan 2021 18:07:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:49:25
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	01 Sep 2020 12:48:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:15:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:03:58
User entered	System	14 Jan 2021 16:03:50
'USA-US051-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	14 Jan 2021 16:03:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User coded data point as SOC: Reproductive system and breast disorders, HLG: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Painful breasts - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 19:33:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 19:33:07
Data point term sent to Coder	System	20 Apr 2021 19:32:20
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
Data point term sent to Coder	System	08 Mar 2021 19:06:32
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:01
User coded data point as SOC: Reproductive system and breast disorders, HLG: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Painful breasts - version MedDRA\23.0.	Coder Import (b) (4)	13 Jan 2021 19:04:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Jan 2021 19:04:03
Data point term sent to Coder	System	13 Jan 2021 18:11:09
User entered 'Worsening of bilateral large painful breast'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:04
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:10
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:12
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:14
User entered '16 Aug 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:15
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User entered empty.	System	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:17
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:18
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 14:23:23
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User entered empty.	System	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:28
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:29
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:32
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:31
User entered 'I'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:35
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:37
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:39
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:50
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:52
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:54
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:55
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:57
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:16:59
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	03 May 2021 12:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:41:28
User closed query 'PV Query: As the last dose of study drug was given, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:49:24
Query 'PV Query: As the last dose of study drug was given, please update the action taken with study drug from none to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:52:59
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 12:51:49
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 12:51:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 12:51:49
User opened query 'PV Query: As the last dose of study drug was given, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:11:34
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:23:29
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User closed query 'PV Query: The subject had received the first dose of study medication prior to event onset. Please consider updating the action taken to none.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 17:00:43
Query 'PV Query: The subject had received the first dose of study medication prior to event onset. Please consider updating the action taken to none.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:26:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 13:26:29
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 13:26:29
User opened query 'PV Query: The subject had received the first dose of study medication prior to event onset. Please consider updating the action taken to none.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 16:15:49
	(b) (4), (b) (6)	27 Jan 2021 21:17:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Jan 2021 18:20:48
User entered 'None (NONE)'	(b) (4)	
	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:17:03
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:01:50
Query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:53:20
User opened query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:11:44
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:17:04
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:17:06
User entered 'I'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:17:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:17:09
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response. When available, please clarify the exact surgery performed for this worsening of bilateral large painful breast. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:01:59
User closed query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:01:55
Query 'PV Query: Thank you for your recent response. When available, please clarify the exact surgery performed for this worsening of bilateral large painful breast. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:53:57
Query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:53:38
User opened query 'PV Query: Thank you for your recent response. When available, please clarify the exact surgery performed for this worsening of bilateral large painful breast. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:12:15
User opened query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:11:54
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User closed query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:16:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:16:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:16:07
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:15:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:23:34
Query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:43:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:43:35
Query 'PV Query: Please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:43:27
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'not done' (Site from Safety).	Chevon Roberts (b) (4)	08 Mar 2021 19:04:06
User closed query 'PV Query: Please clarify the exact surgery performed for this worsening of bilateral large painful breast.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 16:19:39
Query 'PV Query: Please clarify the exact surgery performed for this worsening of bilateral large painful breast.' answered with 'surgeries are listed in conmed procedure log' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 13:41:06
User opened query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:27:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:23:59
User opened query 'PV Query: Please clarify the exact surgery performed for this worsening of bilateral large painful breast.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:23:52
User opened query 'PV Query: Please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:23:45
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:23:38
User entered 'Subject had a preplanned surgery due to painful breast. Subject stated that she had painful breast since UN/UN/2004'	Shanice Bennett (b) (4)	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User entered 'I'	System	13 Jan 2021 18:10:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:51:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User entered 'I'	System	13 Jan 2021 18:10:27

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:32:05
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:05:57
User entered '0'	System	13 Jan 2021 18:10:27



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:25
User entered	(b) (4), (b) (6)	14 Jan 2021 16:06:09
'USA-US051-2021-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 19:33:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 19:33:08
Data point term sent to Coder	System	20 Apr 2021 19:32:20
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
Data point term sent to Coder	System	08 Mar 2021 19:08:38
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 11:55:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Feb 2021 11:55:43
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's Med History condition of INGUINAL HERNIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 01:36:30
Data point term sent to Coder	System	27 Jan 2021 21:24:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:24:42
Query 'Per DM CLR: Please review if this is a worsening of the patient's Med History condition of INGUINAL HERNIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 21:24:21
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 21:24:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'WORSENING OF INGUINAL HERNIA' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 21:24:13
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's Med History condition of INGUINAL HERNIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 05:44:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 18:16:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 18:16:02
Data point term sent to Coder	System	13 Jan 2021 18:15:11
User entered 'Inguinal Hernia'	Shanice Bennett (b) (4) (b) (4)	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:35
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:39
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:40
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History)' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 01:28:18
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:51:25
Query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History)' answered with 'subject had hernia before beginning of study. Procedure was planned and date was given by the subject.' (Site from DM).	Chevon Roberts (b) (4)	20 Apr 2021 22:34:20
Query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' answered with 'Subject had hernia before the study started and informed us that the hernia was getting worse and that surgery was planned. This is the date subject gave us for the AE' (Site from DM).	Chevon Roberts (b) (4)	20 Apr 2021 22:32:15
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History)' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 22:24:53
Query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	20 Apr 2021 22:24:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 22:24:28
Query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' canceled (Site from System).	(b) (4), (b) (6)	20 Apr 2021 22:24:19
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).'	System	20 Apr 2021 19:31:41
(Site from System).		
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		20 Apr 2021 19:31:41
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).'	System	08 Mar 2021 19:07:54
(Site from System).		
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	08 Mar 2021 19:07:54
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
User closed query 'Per CDM: Per CCGs, a complete date is required. Please review and update the start date as the entered data is non-conformant. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:20:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Per CCGs, a complete date is required. Please review and update the start date as the entered data is non-conformant. Thank you' answered with 'UPDATED' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:24:25
	(b) (4), (b) (6)	27 Jan 2021 21:18:42
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	27 Jan 2021 21:11:55
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		27 Jan 2021 21:11:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jan 2021 21:11:55
User entered '16 Jun 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 21:11:55
User opened query 'Per CDM: Per CCGs, a complete date is required. Please review and update the start date as the entered DM data is non-conformant. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:52:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 18:47:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 18:47:57
User entered 'un Mar 2010' (non-conformant).	(b) (4), (b) (6)	15 Jan 2021 18:47:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 18:47:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Jan 2021 18:47:45
User entered ' Mar 2010' (non-conformant).	(b) (4), (b) (6)	15 Jan 2021 18:47:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'UN Mar 2010' (non-conformant).	Shanice Bennett (b) (4) (b) (4)	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 14:23:48
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User entered empty.	System	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:46
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:48
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:51
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User entered empty.	System	13 Jan 2021 18:14:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:55
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:18:56
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Jan 2021 18:14:40
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Jan 2021 18:14:20
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:18:58
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:00
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint Verified.	(b) (4)	
	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:19:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		13 Jan 2021 18:14:40
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		13 Jan 2021 18:14:40
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Jan 2021 18:14:40
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	13 Jan 2021 18:14:20
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:04
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:05
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:07
User entered 'No (N)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:09
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:10
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:12
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:18
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:51:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:20
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:21
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:23
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Jan 2021 18:21:15
	(b) (4)	
User entered 'None (NONE)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:24
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:57:02
Query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'pending paperwork for medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:59:54
User opened query 'PV Query: Thank you for your recent response. When available, please provide treatment given for the event including medical intervention in addition to the surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:12:38
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:27
User entered '0'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:29
User entered 'I'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint activated with code reason code Data required.	(b) (4)	
	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
	(b) (4)	
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:19:32
User entered empty.	Shanice Bennett (b) (4)	13 Jan 2021 18:14:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:57:06
Query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 13:04:10
User opened query 'PV Query: Thank you for your recent response. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:13:21
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:18:44
User closed query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:18:37
User closed query 'PV Query: If event of inguinal hernia is to remain, please clarify the exact surgery performed for this worsening of bilateral large painful breast.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:18:21
User closed query 'PV Query: The event of hernia began prior to informed consent/screening period. Please reassess the validity of this event.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:18:18
User closed query 'PV Query: Was the procedure for the inguinal hernia a planned procedure, with a event start date of Mar 2010, prior to starting IP? If yes, please delete event as planned procedures, with events occurring prior to IP, do not need to be reported as events, or update event term if considered as a worsening of the hernia.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:17:54

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 16:17:49
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:23:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:46:10
Query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' answered with 'Yes this was a planned procedure but the patient stayed over night at the hospital' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:46:04
Query 'PV Query: The event of hernia began prior to informed consent/screening period. Please reassess the validity of this event.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:45:23
Query 'PV Query: If event of inguinal hernia is to remain, please clarify the exact surgery performed for this worsening of bilateral large painful breast.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:45:20
Query 'PV Query: Was the procedure for the inguinal hernia a planned procedure, with a event start date of Mar 2010, prior to starting IP? If yes, please delete event as planned procedures, with events occurring prior to IP, do not need to be reported as events, or update event term if considered as a worsening of the hernia.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:45:18
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records are pending' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:45:15
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 16:14:22
User opened query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 16:14:11
User opened query 'PV Query: If event of inguinal hernia is to remain, please clarify the exact surgery performed for this worsening of bilateral large painful breast.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 16:13:40
User opened query 'PV Query: The event of hernia began prior to informed consent/screening period. Please reassess the validity of this event.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 16:13:26
User opened query 'PV Query: Was the procedure for the inguinal hernia a planned procedure, with a event start date of Mar 2010, prior to starting IP? If yes, please delete event as planned procedures, with events occurring prior to IP, do not need to be reported as events, or update event term if considered as a worsening of the hernia.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:26:43
Query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' canceled (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:26:36
User opened query 'PV Query: Was the procedure for the worsening of bilateral large painful breast and inguinal a planned procedure? If yes, please delete event as planned procedures do not need to be reported as events.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:24:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 20:24:24

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject had a Inguinal Hernia since March of 2010. Subject stated that she didn't want surgery at the time. Subject had surgery with another surgery on the same day. Surgery was at Candler Hospital.'	Shanice Bennett (b) (4) (b) (4)	13 Jan 2021 18:14:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User entered 'I'	System	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User entered 'I'	System	13 Jan 2021 18:14:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:51:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Chevon Roberts (b) (4)	20 Apr 2021 19:31:41
DataPoint inactivated with code reason code Data not required.	Chevon Roberts (b) (4)	08 Mar 2021 19:07:54
User entered '0'	System	13 Jan 2021 18:14:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:51:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	10 Nov 2020 19:47:37
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:49:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:47:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:23:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:23:06
	(b) (4)	
Data point term sent to Coder	System	14 Aug 2020 23:59:24
Datapoint queued for coding (5024686).	System	14 Aug 2020 23:59:12
Data point term sent to Coder	System	29 Jul 2020 15:50:42
User entered 'ATORVASTAIN'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:47:59
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:01
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 15:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 15:52:26
User entered 'HYPERCHOLESTEROLEMIA' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:52:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Jul 2020 15:50:02
	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:03
User entered '40'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:05
User entered 'mg (mg)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:12
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:15
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:17
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:19
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:21
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:30
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:48:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shanice Bennett (b) (4)	29 Jul 2020 15:52:30
answered with 'CORRECT' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 15:50:02
User entered 'UN UNK 2001'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:33
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:35
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:39
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:41
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 15:50:02

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 15:50:02

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 15:50:02

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:01
Data point term sent to Coder	System	23 Feb 2021 15:46:14
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:36
Data point term sent to Coder	System	29 Jul 2020 15:50:43
User entered 'IBUPROFEN'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:50:39

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	



US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'MIGRAINES'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered '800'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	



US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:48:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:50
answered with 'CORRECT' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 15:50:39
User entered 'UN Jan 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:50:39
	(b) (4)	

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 15:50:39

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 15:50:39

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 15:50:39



US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:47:03
Data point term sent to Coder	System	23 Feb 2021 15:46:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:37
Data point term sent to Coder	System	29 Jul 2020 15:51:43
User entered 'ASPIRIN'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 15:51:25

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'CARDIAC PROPHYLAXIS'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered '81'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	



US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:48:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:34
answered with 'CORRECT' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	29 Jul 2020 15:51:25
User entered 'UN UNK 2000'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

US3022063

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:51:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:48:48
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:51:25
	(b) (4)	

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 15:51:25



**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 15:51:25

**US3022063**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 15:51:25

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:51:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:19:41
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 14:35:10
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:48:55
	(b) (4)	

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:20:15
User entered '21 Oct 2020'	(b) (4), (b) (6)	20 Jan 2021 14:35:36

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:20:16
User entered 'breast reduction surgery'	(b) (4), (b) (6)	20 Jan 2021 14:35:36

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 14:25:20
DataPoint Un-verified.	Chevon Roberts (b) (4)	20 Apr 2021 18:14:07
Signature has been broken.	(b) (4) Chevon Roberts (b) (4)	20 Apr 2021 18:14:07
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4) Chevon Roberts (b) (4)	20 Apr 2021 18:14:07
User signature succeeded.	(b) (4) Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:20:17
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	20 Jan 2021 14:35:36

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:51:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:20:19
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:35:36

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:20:22
	(b) (4), (b) (6)	
User entered '21 Oct 2020'	(b) (4), (b) (6)	20 Jan 2021 14:35:53



US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:55:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 21:24:46
User entered 'WORSENING OF INGUINAL HERNIA REPAIR' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 21:24:46
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:20:23
User entered 'inguinal hernia repair'	(b) (4), (b) (6)	20 Jan 2021 14:35:53

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:34
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4)	21 Apr 2021 14:25:24
	(b) (4), (b) (6)	
DataPoint Un-verified.	Chevon Roberts (b) (4)	20 Apr 2021 18:14:01
	(b) (4)	
Signature has been broken.	Chevon Roberts (b) (4)	20 Apr 2021 18:14:01
	(b) (4)	
User entered 'Medical History (MH)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	20 Apr 2021 18:14:01
User signature succeeded.	(b) (4)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:20:25
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	20 Jan 2021 14:35:53

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:51:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:20:26
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:35:53

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:51:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:20:31
	(b) (4), (b) (6)	
User entered '21 Oct 2020'	(b) (4), (b) (6)	20 Jan 2021 14:36:13

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:51:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:20:32
	(b) (4), (b) (6)	
User entered 'panniculectomy'	(b) (4), (b) (6)	20 Jan 2021 14:36:13

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:51:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:35
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
DataPoint Verified.	(b) (4)	21 Apr 2021 14:25:28
	(b) (4), (b) (6)	
DataPoint Un-verified.	Chevon Roberts (b) (4)	20 Apr 2021 18:14:16
	(b) (4)	
Signature has been broken.	Chevon Roberts (b) (4)	20 Apr 2021 18:14:16
	(b) (4)	
User entered 'Medical History (MH)' reason for change: Data Entry Error	Chevon Roberts (b) (4)	20 Apr 2021 18:14:16
User signature succeeded.	(b) (4)	
	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:20:34
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	20 Jan 2021 14:36:13

US3022063

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:51:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:28:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	27 Jan 2021 21:20:36
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:36:13

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:15:29
User entered '14/Jan/2021 11:07'	System	14 Jan 2021 16:07:43



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:15:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:15:34
User entered '19/Jan/2021 07:55'	System	19 Jan 2021 12:56:00

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 18:51:41
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 21:15:36
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 12:56:00

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:49
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '28/Jan/2021 18:51'	(b) (4) System	28 Jan 2021 18:51:53

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 17:01:07
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 18:51:53

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:38
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered '12/Feb/2021 17:01'	(b) (4) System	12 Feb 2021 17:01:20

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:20:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:02:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 17:01:20

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:37:27
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
User entered '21/Apr/2021 12:19'	(b) (4) System	21 Apr 2021 16:19:58



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:37:29
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:15:34
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:20:09
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 16:19:58

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered		
'USA-US051-2021-MRNA-1273-P301000001'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:12
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Yes (Y)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50



**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:19
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'No (N)'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Paul'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:23
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Bradley'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:24
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '340 Eisenhower Dr.'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'Savannah'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:27
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered 'GA'	System	14 Jan 2021 16:03:50

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:51:44**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 21:13:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:07:35
User entered '31406'	System	14 Jan 2021 16:03:50

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 12:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 12:55:51
User entered 'US'	System	14 Jan 2021 16:07:43



US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:51:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 15:02:33
User entered '5'	System	21 Apr 2021 16:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:46:13
	(b) (4)	
User entered '4'	System	12 Feb 2021 17:01:20
User entered '3'	System	28 Jan 2021 18:51:53
User entered '2'	System	19 Jan 2021 12:56:00
User entered '1'	System	14 Jan 2021 16:07:43

**US3022063**

**Folder: SAE USA-US051-2021-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:51:44**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	03 May 2021 12:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 May 2021 03:05:14
User entered '30/Apr/2021 11:02'	System	30 Apr 2021 15:02:33

US3022063

Folder: SAE USA-US051-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:51:44

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	03 May 2021 12:40:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 May 2021 03:05:14
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 15:02:33