

US3022052 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:50:47

All time stamps listed in this document are displayed in GMT

US3022052

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 15:44:54

Generated On: 09 Jun 2021 14:50:47

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Participant ID

US3022052

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

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US3022052

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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 15:44:55

Generated On: 09 Jun 2021 14:50:47

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 15:44:55

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Date of Informed Consent (*dd MMM yyyy*) 28 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 15:44:55

Generated On: 09 Jun 2021 14:50:47

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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 15:44:55

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3022052

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022052

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022052

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022052

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

US3022052

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	CHRONIC STREP THROAT
Start date (dd MMM yyyy)	UN UNK 1977
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1977
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1977
Start Year (derived)	1977
Stop Month and Year (derived)	JAN 1977
Stop Year (derived)	1977

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Condition	DYSPHAGIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	14:02 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 14:02
Height ( <i>xxx.x</i> )	170.0 cm
Weight ( <i>xxx.x</i> )	83.3 kg
BMI ( <i>xxx.x</i> )	28.82353 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 15:44:55

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:44:55

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

GOVERNMENT DESK WORK

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:44:55

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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 COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:44:56

Generated On: 09 Jun 2021 14:50:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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 15:44:56

Generated On: 09 Jun 2021 14:50:47

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 142129

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 15:44:56

Generated On: 09 Jun 2021 14:50:47

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 15:44:56

Generated On: 09 Jun 2021 14:50:47

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)	28 JUL 2020
Time of assessment (00:00-23:59)	14:02 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 14:02
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:44:56

Generated On: 09 Jun 2021 14:50:47

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)	28 JUL 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 15:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 15:44:56

Generated On: 09 Jun 2021 14:50:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:44:56

Generated On: 09 Jun 2021 14:50:47

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) 28 JUL 2020

What was the treatment time? (00:00-23:59) 15:14 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 15:14

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 15:44:56

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JUL 2020
Collection time (00:00-23:59)	14:47 (24 HR)
Collection date and time (derived)	28 JUL 2020 14:47

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:44:56

Generated On: 09 Jun 2021 14:50:47

Collection date (dd MMM yyyy)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	28 JUL 2020 14:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:56

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 JUL 2020 15:48

PC Open Date & Time

28 JUL 2020 15:34

PC Close Date & Time

28 JUL 2020 18:04

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °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	28 JUL 2020 20:14
PC Open Date & Time	28 JUL 2020 18:59
PC Close Date & Time	29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 18:21

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**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

96.6 °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 12:01

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(4)

Generated On: 09 Jun 2021 14:50:47

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**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 17:24

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

02 AUG 2020 00:00

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 13:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 06:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**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

28 JUL 2020 15:50

PC Open Date & Time

28 JUL 2020 15:34

PC Close Date & Time

28 JUL 2020 18:04

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**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

28 JUL 2020 20:14

PC Open Date & Time

28 JUL 2020 18:59

PC Close Date & Time

29 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**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

29 JUL 2020 18:20

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**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

30 JUL 2020 12:00

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**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

31 JUL 2020 17:23

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**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

01 AUG 2020 23:59

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**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

02 AUG 2020 13:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**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

04 AUG 2020 06:55

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**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 ☐

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 15:49
PC Open Date & Time	28 JUL 2020 15:34
PC Close Date & Time	28 JUL 2020 18:04

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**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 ☐

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 20:15
PC Open Date & Time	28 JUL 2020 18:59
PC Close Date & Time	29 JUL 2020 11:59



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 18:20
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 17:23
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 23:59
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 13:14
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**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 ☒

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 06:55
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022052

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022052

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

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*

US3022052

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:58
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	17:16 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:16
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3022052

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:46 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:46

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

US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	16:08 (24 HR)
Collection date and time (derived)	11 SEP 2020 16:08



US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:21	11 SEP 2020 16:21
Nasopharyngeal Swab 2	No		

US3022052

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**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

98.8 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 11 SEP 2020 17:15

PC Open Date & Time 11 SEP 2020 17:06

PC Close Date & Time 11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	12 SEP 2020 09:38
PC Open Date & Time	11 SEP 2020 20:31
PC Close Date & Time	12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**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

98.1 °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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 22:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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**TIMEPOINT**

DAY 6

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

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

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 13:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 7

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

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

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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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:14

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 17:15

PC Open Date & Time

11 SEP 2020 17:06

PC Close Date & Time

11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**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

12 SEP 2020 09:38

PC Open Date & Time

11 SEP 2020 20:31

PC Close Date & Time

12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**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

15 SEP 2020 22:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 13:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:14

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**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 ☐

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:10
PC Open Date & Time	11 SEP 2020 17:06
PC Close Date & Time	11 SEP 2020 19:36

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**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 ☐

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 09:39
PC Open Date & Time	11 SEP 2020 20:31
PC Close Date & Time	12 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**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 ☒

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 13:31
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:14
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3022052

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022052

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:15
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022052

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 OCT 2020
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	09 OCT 2020 10:32

US3022052

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:58

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

27 SEP 2020 08:42:56

Patient Cloud Open Date & Time

27 SEP 2020 00:01

Patient Cloud Close Date & Time

01 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

04 OCT 2020 07:22:34

Patient Cloud Open Date & Time

04 OCT 2020 00:01

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 OCT 2020 18:00:24
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 NOV 2020 18:07:59
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

10 NOV 2020 12:07:56

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

17 NOV 2020 12:45:14

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 18:21:26

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 08:49:31

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

10 DEC 2020 06:56:04

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:01:02

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

02 JAN 2021 12:14:05

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

09 JAN 2021 14:51:58

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

14 JAN 2021 06:47:05

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

21 JAN 2021 06:52:35

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

28 JAN 2021 06:54:33

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

04 FEB 2021 07:11:12

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

13 FEB 2021 13:01:18

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

25 FEB 2021 11:28:04

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 12:48:49

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

11 MAR 2021 11:25:31

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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

20 MAR 2021 12:00:35

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 12:33:16

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 18:01:20

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 07:20:27

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 17:59:25

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

Date and time of submission

25 APR 2021 18:46:14

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

Date and time of submission

29 APR 2021 06:59:38

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 299

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐  
Yes ☐

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	23 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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°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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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14 MAR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

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**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐  
Yes ☐

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐  
Yes ☐

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59



US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

US3022052

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

**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 ☐ Yes ☐

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

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3022052

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:50:47

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 12:49:03

US3022052

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3022052

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

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 \_\_\_\_\_

US3022052

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:12:07

Generated On: 09 Jun 2021 14:50:47

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) \_\_\_\_\_

US3022052

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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



US3022052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	09:53 (24 HR)
Collection date and time (derived)	24 FEB 2021 09:53

US3022052

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:55:24

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022052

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022052

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022052**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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*

**US3022052**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3022052**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:50:47**

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"/>

**US3022052**

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

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

**Generated On: 09 Jun 2021 14:50:47**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3022052

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

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:00:56

Generated On: 09 Jun 2021 14:50:47

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

Visit date (dd MMM yyyy)	24 MAR 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3022052

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 23:00:56

Generated On: 09 Jun 2021 14:50:47

Date of updated informed consent ( <i>dd MMM yyyy</i> )	24 MAR 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> )	24 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	<input type="checkbox"/>
Continuing with mRNA-1273	<input type="checkbox"/>

US3022052

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:00:56

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

24 MAR 2021 08:20

US3022052

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Mar 2021 23:00:56

Generated On: 09 Jun 2021 14:50:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00 - 23:59)	08:29
Collection Date and Time (derived)	24 MAR 2021 08:29

US3022052

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 15:44:54

Generated On: 09 Jun 2021 14:50:47

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

AEID	USA-US051-2020-MRNA-1273-P30 1000010
Adverse event	ESOPHAGEAL CANCER
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)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

SUBJECT REPORTED ON DAY 85  
SAFETY PHONE CALL THAT HE  
WAS DIAGNOSED WITH  
ESOPHAGEAL CANCER AND  
HAS AN UPCOMING SURGERY.  
CALLED AND FOLLOWED WITH  
PATIENT. HE REPORTS OVER  
THE PAST 3 YEARS HE HAS  
HAD DIFFICULTY IN  
SWALLOWING. HE STATES HE  
PREVIOUSLY NEVER SOUGHT  
CARE FOR THIS TREATED SELF  
FOR WHAT HE THOUGHT WAS  
ACID REFLUX. SUBJECT  
REPORTS HE HAD AN  
ENDOSCOPE ON 15OCT2020  
AND HAD AN ESOPHAGEAL  
TISSUE BIOPSIED. HE  
RECEIVED THE RESULTS OF  
ESOPHAGEAL CANCER AND  
HAS SURGERY SCHEDULED  
FOR 09NOV2020 FOR AN  
ESOPHAGECTOMY AND  
GASTROSTOMY TUBE PLACED  
FOR FEEDING. HE DENIES  
CHEMO OR RADIATION  
PLANNED AT THIS TIME.

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



US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

AEID	USA-US051-2020-MRNA-1273-P30 1000010
Adverse event	ESOPHAGEAL TEAR
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)	15 OCT 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)	18 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)	15 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	18 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

---

THIS REPORT WAS INITIALLY  
REPORTED AS ESOPHAGEAL  
CANCER. AFTER FURTHER  
REVIEW WITH THE SUBJECT,  
THE SAE WAS NOT RELATED  
TO THE DIAGNOSIS OF  
ESOPHAGEAL CANCER BUT  
RATHER A COMPLICATION OF  
THE ESOPHAGEAL BIOPSY  
REQUIRING EMERGENCY  
SURGERY AND HOSPITAL  
ADMISSION.

---

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

---

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

AEID	
Adverse event	BARRETTS ESOPHGEUS
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)	UN AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

---

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

Yes ☒

No ☐

---

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

---

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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Name of Medication JUNUVIA

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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Name of Medication LEVOTHYROXIN

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	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)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication PNEUMOCOCCAL VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication LANSOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ESOPHAGEAL CANCER

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication REGLIN

Prophylaxis Yes ☐  
No ☒

Indication ESOPHAGEAL CANCER

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ESOPHAGEAL CANCER

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 22:12:06

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication AMOXICILLIN/CAVULANATE

Prophylaxis Yes ☐  
No ☒

Indication ESOPHAGEAL TEAR

Dose per administration 875/125

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

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EAB) (1725)

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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)

358 of 2194

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

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



US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 15:44:55

Generated On: 09 Jun 2021 14:50:47

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 NOV 2020	GASTROSTOMY TUBE	Adverse Event	
09 NOV 2020	ESOPHAGECTOMY	Adverse Event	
10 FEB 2021	GASTROSTOMY TUBE REMOVED	Adverse Event	
16 OCT 2020	ESOPHAGEAL STENT PLACEMENT	Adverse Event	
16 OCT 2020	ESOPHAGOGASTRO-DUODENOSC OPY	Adverse Event	
16 OCT 2020	CHEST TUBE PLACEMENT	Adverse Event	
16 OCT 2020	BRONCHOSCOPY	Adverse Event	
16 OCT 2020	RIGHT THORACOSCOPIC EVACUATION PLEURAL EFFUSION	Adverse Event	
16 OCT 2020	MEDIASTINAL DRAINAGE	Adverse Event	
16 OCT 2020	THORACIC CAVITY FIELD BLOCK	Adverse Event	
15 OCT 2020	ESOPHAGOGASTRO-DUODENOSC OPY	Adverse Event	
15 OCT 2020	ESOPHAGEAL TISSUE BIOPSY	Adverse Event	

US3022052

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:50:47

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

US3022052

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:50:47

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 ☐

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	06/NOV/2020 16:49
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	11/NOV/2020 15:03
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	16/NOV/2020 16:14
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



US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	25/FEB/2021 18:28
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	01/MAR/2021 09:57
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:13
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	22/MAR/2021 10:40
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

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (8)

Data signed: (b) (4) 13 Apr 2021 22:12:06

Generated On: 09 Jun 2021 14:50:47

SAEID	USA-US051-2020-MRNA-1273-P301000010
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 checked="" type="radio"/> No <input 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)	8
Date of submission (Pre-filled from custom function)	13/APR/2021 10:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022052 (Prod: Meridian Clinical Research-Savannah)

**US3022052**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:50:47**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'US3022052'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Jul 2020 17:59:10

**US3022052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:32



**US3022052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 17:59:11

US3022052

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:47

[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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:32

**US3022052**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'SCRN'	System	28 Jul 2020 19:42:32

US3022052

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Jul 2020 17:59:11

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '55'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'YEARS'	System	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '55'	System	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Male (M)'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47



US3022052

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'I'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47



**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:47**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	Shanice Bennett (b) (4)	28 Jul 2020 19:42:47

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jul 2020'	System	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2020'	System	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16



**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:16

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Jul 2020 17:59:11

**US3022052**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:47**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'I'	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:50:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:50:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:56:32

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:42:43
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'updated In con med log' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:14:56
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:22:19
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 20:58:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 20:58:59
Data point term sent to Coder	System	28 Jul 2020 20:57:21
User entered 'Diabetes Mellitus Type II'	Morgan Deal (b) (4)	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 2014'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:56:55



**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:56:55

US3022052

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4)	28 Jul 2020 20:56:55
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 2014'	System	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2014'	System	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:56:55

**US3022052**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:56:55



US3022052

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:42:52
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' answered with 'updated in con med log' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:15:05
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:22:44
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:58:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:58:59
Data point term sent to Coder	System	28 Jul 2020 20:57:21
User entered 'Hypertension'	Morgan Deal (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 2017'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 2017'	System	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2017'	System	28 Jul 2020 20:57:19



**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:57:19

**US3022052**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:57:19

US3022052

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 20:59:00
Data point term sent to Coder	System	28 Jul 2020 20:58:22
User entered 'Hyperlipidemia'	Morgan Deal (b) (4)	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 2013'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:57:59
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:57:59
	Morgan Deal (b) (4)	
	(b) (4)	



**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 2013'	System	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2013'	System	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:57:59

**US3022052**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:57:59

US3022052

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:50:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:43:00
' (Site from DM).		
Query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.	(b) (4), (b) (6)	02 Oct 2020 12:15:15
' answered with 'updated in con med log ' (Site from DM).		
User opened query 'Per DM CLR: Please review and please note that there is no listed treatment for this condition and treatment is expected. Please review and update to record the corresponding treatment if applicable. Otherwise, clarify reason why no treatment is needed.	(b) (4), (b) (6)	01 Sep 2020 10:23:00
' (Site from DM).		
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 21:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 21:01:02
Data point term sent to Coder	System	28 Jul 2020 20:59:22
User entered 'Hypothyroidism'	Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 2014'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:58:46
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:58:46



**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:58:46
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 2014'	System	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2014'	System	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:58:46

**US3022052**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	28 Jul 2020 20:58:46

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:01:02
Data point term sent to Coder	System	28 Jul 2020 20:59:23
User entered 'Tonsillectomy'	Morgan Deal (b) (4)	28 Jul 2020 20:59:14
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 1977'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:59:14



**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:59:14

US3022052

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:50:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jul 2020 20:59:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 20:59:19
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	28 Jul 2020 20:59:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jul 2020 20:59:14
User entered empty.	System	28 Jul 2020 20:59:14
	Morgan Deal (b) (4)	28 Jul 2020 20:59:14
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 1977'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:59:14

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:59:14

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 1977'	System	28 Jul 2020 20:59:14

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '1977'	System	28 Jul 2020 20:59:14

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 1977'	System	28 Jul 2020 20:59:14

**US3022052**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '1977'	System	28 Jul 2020 20:59:14



US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:50:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 12:47:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 12:47:45
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal sore throat - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:47:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 21:47:58
Data point term sent to Coder	System	28 Jul 2020 21:00:24
User entered 'Chronic Strep Throat'	Morgan Deal (b) (4)	28 Jul 2020 20:59:47
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 1977'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 20:59:47

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:59:47
	Morgan Deal (b) (4)	
	(b) (4)	

US3022052

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:50:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jul 2020 20:59:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 20:59:50
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4)	28 Jul 2020 20:59:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Jul 2020 20:59:47
User entered empty.	System	28 Jul 2020 20:59:47
	Morgan Deal (b) (4)	28 Jul 2020 20:59:47
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'un UNK 1977'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 20:59:47

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 20:59:47
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 1977'	System	28 Jul 2020 20:59:47

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '1977'	System	28 Jul 2020 20:59:47



**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 1977'	System	28 Jul 2020 20:59:47

**US3022052**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '1977'	System	28 Jul 2020 20:59:47

US3022052

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:50:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Dysphagia, LLT: Dysphagia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 21:06:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 21:06:07
Data point term sent to Coder	System	08 Apr 2021 21:04:37
User entered 'Dysphagia'	(b) (4), (b) (6)	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 21:03:51



**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'Jan 2017'	System	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '2017'	System	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	08 Apr 2021 21:03:51

**US3022052**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered empty.	System	08 Apr 2021 21:03:51

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per CDM: Per CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be recorded at Screening. All other Vital signs should be marked as 'ND'. Please review, reconcile and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:45:46
Query 'Per CDM: Per CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be recorded at Screening. All other Vital signs should be marked as 'ND'. Please review, reconcile and update this page accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:29:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:04
User opened query 'Per CDM: Per CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be recorded at Screening. All other Vital signs should be marked as 'ND'. Please review, reconcile and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 13:53:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered 'Yes (Y)'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	16 Dec 2020 14:29:32
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '28 Jul 2020'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:00:34
	(b) (4)	

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered '14:02' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '14:02'	(b) (4)	28 Jul 2020 21:00:34
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '28 Jul 2020 14:02'	System	16 Dec 2020 14:29:32
User entered empty.	System	26 Aug 2020 17:27:05
User entered '28 Jul 2020 14:02'	System	28 Jul 2020 21:00:34



US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '170.0' cm reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '170' cm	Morgan Deal (b) (4)	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '83.3' kg reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '83.3' kg	Morgan Deal (b) (4)	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

**US3022052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered '28.82353'	System	16 Dec 2020 14:29:04
User entered empty.	System	26 Aug 2020 17:27:05
User entered '28.8'	System	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'kg/m2'	System	16 Dec 2020 14:29:04
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'kg/m2'	System	28 Jul 2020 21:00:34
DataPoint set to visible.	System	28 Jul 2020 19:43:30

US3022052

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User closed query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 04:17:22
Query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	26 Aug 2020 17:27:15
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User opened query 'Per CDM: requery : please note as screening and dosing is done on same date the above mentioned fields should be "ND" as per CCGs. Kindly update ' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 08:19:23
User closed query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 08:19:23
Query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	24 Aug 2020 16:24:51
User opened query 'Per CDM: per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Aug 2020 21:07:03

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered 'Oral (Oral)'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

**US3022052**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4)	28 Jul 2020 21:00:34
	Morgan Deal (b) (4)	
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '63'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'bpm'	System	16 Dec 2020 14:29:32
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'bpm'	System	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '15'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'breaths/min'	System	16 Dec 2020 14:29:32
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'breaths/min'	System	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '122'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'mmHg'	System	16 Dec 2020 14:29:32
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'mmHg'	System	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Dec 2020 14:29:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 14:29:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 14:29:32
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Dec 2020 14:29:04
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 17:27:05
User entered '72'	Morgan Deal (b) (4)	28 Jul 2020 21:00:34

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User entered 'mmHg'	System	16 Dec 2020 14:29:32
User entered empty.	System	26 Aug 2020 17:27:05
User entered 'mmHg'	System	28 Jul 2020 21:00:34



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:00:42
	Morgan Deal (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	(b) (4)	28 Jul 2020 21:00:42
	Morgan Deal (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:47

[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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4)	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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**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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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**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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53



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Folder: Screening

Form: Risk of Exposure

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Aug 2020 16:24:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 16:24:12
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	24 Aug 2020 16:24:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	28 Jul 2020 21:01:53
	(b) (4)	

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Folder: Screening

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	
	(b) (4)	



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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Government desk work'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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Folder: Screening

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:01:53

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

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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 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4)	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'I'	(b) (4)	28 Jul 2020 21:01:53
	Morgan Deal (b) (4)	
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:08:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Lives in community with ongoing person to person transmissin'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:01:53

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:02:46
	Morgan Deal (b) (4)	
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:02:46

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Clinic (Clinic)'	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:02:46

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'VISIT1'	System	28 Jul 2020 21:02:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Jul 2020 18:54:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:08:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:08:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 18:54:24
User entered '142129' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Jul 2020 18:54:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 18:54:24



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:47

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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 13:35:41
Query 'Complete page to confirm that the subject was assigned to the correct cohort.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	22 Aug 2020 01:27:56
User entered 'No (N)'	(b) (4)	22 Aug 2020 01:27:32
User opened query 'Complete page to confirm that the subject was assigned to the correct cohort.' (Site from CRA).	(b) (4), (b) (6)	03 Aug 2020 23:59:40

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:47

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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Shanice Bennett (b) (4)	22 Aug 2020 01:27:32

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:50:47**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Shanice Bennett (b) (4)	22 Aug 2020 01:27:32

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:50:47**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	22 Aug 2020 01:27:32

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:50:47**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	Shanice Bennett (b) (4)	22 Aug 2020 01:27:32

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
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) (4), (b) (6)	04 Nov 2020 08:32:03
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) (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:04:43
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 10:46:02
User entered '170' cm	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Morgan Deal (b) (4)	24 Aug 2020 16:26:48
	(b) (4)	

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
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) (4), (b) (6)	04 Nov 2020 08:32:03
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) (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:04:43
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 10:46:02
User entered '170' cm	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48



US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48
	(b) (4)	

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '14:02'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '28 Jul 2020 14:02'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '36.8' C	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48



**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '63'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'bpm'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '15'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'breaths/min'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '122'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'mmHg'	System	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '72'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48



US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
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) (4), (b) (6)	04 Nov 2020 08:32:03
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) (b) (4)	03 Nov 2020 16:04:50
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:04:43
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 10:46:02
User entered '170' cm	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 16:04:43
User entered '83.3' kg	Morgan Deal (b) (4)	24 Aug 2020 16:26:48
	(b) (4)	

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '15:50'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '28 Jul 2020 15:50'	System	24 Aug 2020 16:26:48



US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '36.7' C	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '80'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'bpm'	System	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '15'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'breaths/min'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '126'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'mmHg'	System	24 Aug 2020 16:26:48

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered '70'	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'mmHg'	System	24 Aug 2020 16:26:48

US3022052

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4)	28 Jul 2020 21:02:56

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	(b) (4)	28 Jul 2020 21:02:56
	Morgan Deal (b) (4)	
	(b) (4)	

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per CDM: Please complete the Vital Signs Dosing form' (Site from DM).	(b) (4)	25 Aug 2020 04:15:51
Query 'Per CDM: Please complete the Vital Signs Dosing form' answered with 'up[dated]' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 04:15:51
User opened query 'Per CDM: Please complete the Vital Signs Dosing form' (Site from DM).	Shanice Bennett (b) (4)	24 Aug 2020 16:27:02
User entered 'Yes (Y)'	(b) (4)	24 Aug 2020 16:27:02
	(b) (4), (b) (6)	23 Aug 2020 21:06:21
	(b) (4)	28 Jul 2020 19:43:58
	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58
	(b) (4)	28 Jul 2020 19:43:58

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:50:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58



US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '28 Jul 2020'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '15:14'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:50:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '28 Jul 2020 15:14'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Right Arm (RIGHT ARM)'	Shanice Bennett (b) (4)	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'ONCE'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 19:43:58

US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:03:18
	Morgan Deal (b) (4)	
	(b) (4)	



US3022052

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:54:53
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '28JUL2020 is the correct date' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 13:13:58
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JUL2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 27JUL2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:39:30
User entered '28 Jul 2020'	Morgan Deal (b) (4)	28 Jul 2020 21:03:18

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '14:47'	(b) (4)	28 Jul 2020 21:03:18
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '28 Jul 2020 14:47'	System	28 Jul 2020 21:03:18

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however date is recorded as 28JUL2020 in EDC. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:34:47
Query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however date is recorded as 28JUL2020 in EDC. Please review and clarify.' answered with '28JUL2020 is the correct date ' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 13:13:39
User opened query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however date is recorded as 28JUL2020 in EDC. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:21:18
Query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however there is no Unscheduled Visit date is recorded as 28JUL2020 in EDC. Please review and clarify.' canceled (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:20:57
User opened query 'Per GCL Lab Rec: it appears GCL has date of 27JUL2020; however there is no Unscheduled Visit date is recorded as 28JUL2020 in EDC. Please review and clarify.' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:20:44
User entered '28 Jul 2020'	Morgan Deal (b) (4)	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:03:35
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '14:40'	(b) (4)	28 Jul 2020 21:03:35
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '28 Jul 2020 14:40'	System	28 Jul 2020 21:03:35



**US3022052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4)	28 Jul 2020 21:03:35
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) Morgan Deal (b) (4) (b) (4)	28 Jul 2020 21:03:35

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered empty.	System	28 Jul 2020 21:03:35

US3022052

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4)	28 Jul 2020 21:03:39
	Morgan Deal (b) (4)	
	(b) (4)	

**US3022052**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	28 Jul 2020 21:03:39

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561' User entered 'Yes (Y)'	System	28 Jul 2020 19:48:54
	System	28 Jul 2020 19:48:54



US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561' User entered '98.1'	System	28 Jul 2020 19:48:54
	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561' User entered 'No (N)'	System	28 Jul 2020 19:48:54
	System	28 Jul 2020 19:48:54

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:48:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '759d6f0a-52c1-4bda-bfb4-1ada6c9f0561' User entered '28 Jul 2020 15:48'	System	28 Jul 2020 19:48:54
	System	28 Jul 2020 19:48:54

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:13:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8' User entered 'Yes (Y)'	System	29 Jul 2020 00:14:17
	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8' User entered '97.2'	System	29 Jul 2020 00:14:17
	System	29 Jul 2020 00:14:17



US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8'	System	29 Jul 2020 00:14:17
User entered 'No (N)'	System	29 Jul 2020 00:14:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '53e711f6-2a6c-47ca-b2c2-ece0d598cac8' User entered '28 Jul 2020 20:14'	System	29 Jul 2020 00:14:17
	System	29 Jul 2020 00:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031' User entered 'Yes (Y)'	System	29 Jul 2020 22:21:26
	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031' User entered '97.4'	System	29 Jul 2020 22:21:26
	System	29 Jul 2020 22:21:26

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031'	System	29 Jul 2020 22:21:26
User entered 'No (N)'	System	29 Jul 2020 22:21:26



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:21:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73db96b4-1e76-4df1-8606-662429811031' User entered '29 Jul 2020 18:21'	System	29 Jul 2020 22:21:26
	System	29 Jul 2020 22:21:26

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654' User entered 'Yes (Y)'	System	30 Jul 2020 16:01:45
	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654' User entered '96.6'	System	30 Jul 2020 16:01:45
	System	30 Jul 2020 16:01:45

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654' User entered 'No (N)'	System	30 Jul 2020 16:01:45
	System	30 Jul 2020 16:01:45

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:01:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '9bdda2df-f51b-44a3-9226-f25c902e8654' User entered '30 Jul 2020 12:01'	System	30 Jul 2020 16:01:45
	System	30 Jul 2020 16:01:45



US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1' User entered 'Yes (Y)'	System	31 Jul 2020 21:24:41
	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1' User entered '98.5'	System	31 Jul 2020 21:24:41
	System	31 Jul 2020 21:24:41

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1' User entered 'No (N)'	System	31 Jul 2020 21:24:41
	System	31 Jul 2020 21:24:41

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:24:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '69e0ebdd-07b9-4703-9e8c-db4bed02fcc1' User entered '31 Jul 2020 17:24'	System	31 Jul 2020 21:24:41
	System	31 Jul 2020 21:24:41

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58



US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e' User entered 'Yes (Y)'	System	02 Aug 2020 04:00:18
	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e' User entered '97.9'	System	02 Aug 2020 04:00:18
	System	02 Aug 2020 04:00:18

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e' User entered 'No (N)'	System	02 Aug 2020 04:00:18
	System	02 Aug 2020 04:00:18

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T00:00:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a4fd5a46-0432-4102-831c-982f3fc2e81e'	System	02 Aug 2020 04:00:18
User entered '02 Aug 2020 00:00'	System	02 Aug 2020 04:00:18

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58



US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8' User entered 'Yes (Y)'	System	02 Aug 2020 17:14:04
	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8' User entered '97.8'	System	02 Aug 2020 17:14:04
	System	02 Aug 2020 17:14:04

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:13:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8' User entered 'No (N)'	System	02 Aug 2020 17:14:04
	System	02 Aug 2020 17:14:04

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1cabe0b2-5895-45c8-b4be-615b8a8955a8' User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:04
	System	02 Aug 2020 17:14:04

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b' User entered 'Yes (Y)'	System	04 Aug 2020 10:56:17
	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b' User entered '97.8'	System	04 Aug 2020 10:56:17
	System	04 Aug 2020 10:56:17

US3022052

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b'	System	04 Aug 2020 10:56:17
User entered 'No (N)'	System	04 Aug 2020 10:56:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:56:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '45ffac18-a385-433e-8d22-cfb98f45510b' User entered '04 Aug 2020 06:56'	System	04 Aug 2020 10:56:17
	System	04 Aug 2020 10:56:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered 'None (1)'	System	28 Jul 2020 19:50:07
	System	28 Jul 2020 19:50:07



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered 'No (N)'	System	28 Jul 2020 19:50:07
	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered 'No (N)'	System	28 Jul 2020 19:50:07
	System	28 Jul 2020 19:50:07

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:50:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae'	System	28 Jul 2020 19:50:07
User entered 'None (1)'	System	28 Jul 2020 19:50:07

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:50:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '55ea9beb-0458-45d6-a4e9-d5d711676bae' User entered '28 Jul 2020 15:50'	System	28 Jul 2020 19:50:07
	System	28 Jul 2020 19:50:07

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'None (1)'	System	29 Jul 2020 00:14:40



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79' User entered 'No (N)'	System	29 Jul 2020 00:14:40
	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'No (N)'	System	29 Jul 2020 00:14:40

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79'	System	29 Jul 2020 00:14:40
User entered 'None (1)'	System	29 Jul 2020 00:14:40

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fc307ab6-51ad-4d48-a420-f1affd38ba79' User entered '28 Jul 2020 20:14'	System	29 Jul 2020 00:14:40
	System	29 Jul 2020 00:14:40

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'None (1)'	System	29 Jul 2020 22:20:32



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'No (N)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'No (N)'	System	29 Jul 2020 22:20:32

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered 'None (1)'	System	29 Jul 2020 22:20:32

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1468ff8b-3a17-4dc8-a337-b6f7326bee92'	System	29 Jul 2020 22:20:32
User entered '29 Jul 2020 18:20'	System	29 Jul 2020 22:20:32

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'None (1)'	System	30 Jul 2020 16:00:58



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'No (N)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'No (N)'	System	30 Jul 2020 16:00:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered 'None (1)'	System	30 Jul 2020 16:00:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4c3f508f-a29f-4e1c-bf6d-ac94bb4b6407'	System	30 Jul 2020 16:00:58
User entered '30 Jul 2020 12:00'	System	30 Jul 2020 16:00:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'None (1)'	System	31 Jul 2020 21:23:21



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92' User entered 'No (N)'	System	31 Jul 2020 21:23:21
	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'No (N)'	System	31 Jul 2020 21:23:21

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered 'None (1)'	System	31 Jul 2020 21:23:21

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '14ecce10-565d-4b27-a470-1f179be69a92'	System	31 Jul 2020 21:23:21
User entered '31 Jul 2020 17:23'	System	31 Jul 2020 21:23:21

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d'	System	02 Aug 2020 03:59:48
User entered 'None (1)'	System	02 Aug 2020 03:59:48



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d' User entered 'No (N)'	System	02 Aug 2020 03:59:48
	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d' User entered 'No (N)'	System	02 Aug 2020 03:59:48
	System	02 Aug 2020 03:59:48

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d' User entered 'None (1)'	System	02 Aug 2020 03:59:48
	System	02 Aug 2020 03:59:48

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '73f15eaa-2d13-46d3-88e2-7dff39cbd24d' User entered '01 Aug 2020 23:59'	System	02 Aug 2020 03:59:48
	System	02 Aug 2020 03:59:48

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b' User entered 'None (1)'	System	02 Aug 2020 17:14:30
	System	02 Aug 2020 17:14:30



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b' User entered 'No (N)'	System	02 Aug 2020 17:14:30
	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b' User entered 'No (N)'	System	02 Aug 2020 17:14:30
	System	02 Aug 2020 17:14:30

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b' User entered 'None (1)'	System	02 Aug 2020 17:14:30
	System	02 Aug 2020 17:14:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8bf583e4-f78d-4b95-b277-42ddf75a4a9b' User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:30
	System	02 Aug 2020 17:14:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24' User entered 'None (1)'	System	04 Aug 2020 10:55:46
	System	04 Aug 2020 10:55:46



US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24' User entered 'No (N)'	System	04 Aug 2020 10:55:46
	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24' User entered 'No (N)'	System	04 Aug 2020 10:55:46
	System	04 Aug 2020 10:55:46

US3022052

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24' User entered 'None (1)'	System	04 Aug 2020 10:55:46
	System	04 Aug 2020 10:55:46

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ddf2b6f3-9815-46e0-9bf5-73e58bd3ad24' User entered '04 Aug 2020 06:55'	System	04 Aug 2020 10:55:46
	System	04 Aug 2020 10:55:46

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:18', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'None (0)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered 'No (N)'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T15:49:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd67bd63e-921e-41fd-8515-2e3948531fee' User entered '28 Jul 2020 15:49'	System	28 Jul 2020 19:49:30
	System	28 Jul 2020 19:49:30

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 15:34'	System	28 Jul 2020 19:43:58



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:04'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:14:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'None (0)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:15:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered 'No (N)'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-28T20:15:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e9bdc3-e189-4667-829f-7928866d7c71' User entered '28 Jul 2020 20:15'	System	29 Jul 2020 00:15:06
	System	29 Jul 2020 00:15:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '28 Jul 2020 18:59'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 2'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'None (0)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered 'No (N)'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-29T18:20:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7726986c-5d94-473d-b39d-c5476041934b' User entered '29 Jul 2020 18:20'	System	29 Jul 2020 22:20:50
	System	29 Jul 2020 22:20:50

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 3'	System	28 Jul 2020 19:43:58



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'None (0)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered 'No (N)'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-30T12:00:39', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e13d4a6c-9f77-4ed1-a270-2b4a77d08c67' User entered '30 Jul 2020 12:00'	System	30 Jul 2020 16:00:42
	System	30 Jul 2020 16:00:42



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 4'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'None (0)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:22:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered 'No (N)'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-07-31T17:23:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'cf2b884b-1dba-44a5-be76-917ffcce5fa2' User entered '31 Jul 2020 17:23'	System	31 Jul 2020 21:23:06
	System	31 Jul 2020 21:23:06

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 5'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'None (0)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered 'No (N)'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-01T23:59:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '177829e1-556e-4074-b72c-990ce2a3af2c' User entered '01 Aug 2020 23:59'	System	02 Aug 2020 03:59:36
	System	02 Aug 2020 03:59:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 19:43:58



US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 6'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'None (0)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:13', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered 'No (N)'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-02T13:14:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '30a992d0-4436-4b5d-a6c5-82a82e73c1a4' User entered '02 Aug 2020 13:14'	System	02 Aug 2020 17:14:17
	System	02 Aug 2020 17:14:17

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 7'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:18', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:21', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36



**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'None (0)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

US3022052

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered 'No (N)'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-08-04T06:55:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '0452eab6-0175-44ce-b5e2-46b93d2a42df' User entered '04 Aug 2020 06:55'	System	04 Aug 2020 10:55:36
	System	04 Aug 2020 10:55:36

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 19:43:58

**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '07 Aug 2020'	Shanice Bennett (b) (4)	12 Aug 2020 20:31:47



**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:31:47

**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	12 Aug 2020 20:31:47

**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	12 Aug 2020 20:32:02

**US3022052**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	12 Aug 2020 20:32:02

**US3022052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

**US3022052**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '12 Aug 2020'	Shanice Bennett (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:32:14

US3022052

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	Shanice Bennett (b) (4)	12 Aug 2020 20:32:14



**US3022052**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	12 Aug 2020 20:32:19

**US3022052**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	12 Aug 2020 20:32:19

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:06:01

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:06:01

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 19:06:01

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:01

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:06:05

**US3022052**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	19 Aug 2020 19:06:05



**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:04:27
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CORRECT' (Site from System).	Shanice Bennett (b) (4)	24 Sep 2020 00:57:24
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 16:44:39
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 16:44:39

US3022052

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:47

[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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:44:39

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'VISIT2'	System	22 Sep 2020 16:44:39

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '15:58'	(b) (4), (b) (6)	22 Sep 2020 17:36:42



US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered '11 Sep 2020 15:58'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '37.1' C	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '72'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'bpm'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '16'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'breaths/min'	System	22 Sep 2020 17:36:42



**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '131'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '69'	(b) (4), (b) (6)	22 Sep 2020 17:36:42

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	22 Sep 2020 17:36:42

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '17:16'	(b) (4), (b) (6)	22 Sep 2020 17:41:26



US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered '11 Sep 2020 17:16'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '37.1' C	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '71'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'bpm'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '15'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'breaths/min'	System	22 Sep 2020 17:41:26



US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '134'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '89'	(b) (4), (b) (6)	22 Sep 2020 17:41:26

US3022052

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	22 Sep 2020 17:41:26

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:39:02

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:39:02

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08



US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

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 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '16:46'	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '11 Sep 2020 16:46'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Right Arm (RIGHT ARM)'	Chevon Roberts (b) (4)	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'ONCE'	System	11 Sep 2020 21:00:08

US3022052

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 21:00:08



US3022052

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '16:08'	(b) (4), (b) (6)	22 Sep 2020 17:39:22

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '11 Sep 2020 16:08'	System	22 Sep 2020 17:39:22

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:39:44

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 17:39:44

US3022052

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:39:44

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '16:21'	(b) (4), (b) (6)	22 Sep 2020 17:39:44



**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered '11 Sep 2020 16:21'	System	22 Sep 2020 17:39:44

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 17:40:32

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 17:40:32

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:40:32

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered empty.	System	22 Sep 2020 17:40:32

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:40:39

**US3022052**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	22 Sep 2020 17:40:39

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:11:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5' User entered 'Yes (Y)'	System	11 Sep 2020 21:15:06
	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:14:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5' User entered '98.8'	System	11 Sep 2020 21:15:06
	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5' User entered 'No (N)'	System	11 Sep 2020 21:15:06
	System	11 Sep 2020 21:15:06

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '565cec73-0516-4bed-bcbd-3fb22f77a8b5' User entered '11 Sep 2020 17:15'	System	11 Sep 2020 21:15:06
	System	11 Sep 2020 21:15:06

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:37:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695' User entered 'Yes (Y)'	System	12 Sep 2020 13:38:07
	System	12 Sep 2020 13:38:07



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:37:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695' User entered '98.7'	System	12 Sep 2020 13:38:07
	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered 'No (N)'	System	12 Sep 2020 13:38:07

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'fa6470a3-6ef6-4af3-8bcf-adf77b993695'	System	12 Sep 2020 13:38:07
User entered '12 Sep 2020 09:38'	System	12 Sep 2020 13:38:07

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:01:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da' User entered 'Yes (Y)'	System	12 Sep 2020 16:06:48
	System	12 Sep 2020 16:06:48

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da' User entered '98.4'	System	12 Sep 2020 16:06:48
	System	12 Sep 2020 16:06:48



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da' User entered 'No (N)'	System	12 Sep 2020 16:06:48
	System	12 Sep 2020 16:06:48

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '228187b7-cce2-43fe-9688-59fd039814da' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:06:48
	System	12 Sep 2020 16:06:48

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:00:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered 'Yes (Y)'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '96.8'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered 'Yes (Y)'	System	13 Sep 2020 16:02:42



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'attempted to reacg subject' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 20:44:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 21:23:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '1'	System	13 Sep 2020 16:02:42

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:01:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '0'	System	13 Sep 2020 16:02:42

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b62d5a16-8c79-41ac-ae18-ebfb63227cf2'	System	13 Sep 2020 16:02:42
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 16:02:42

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df' User entered 'Yes (Y)'	System	14 Sep 2020 16:04:03
	System	14 Sep 2020 16:04:03

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:06', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df' User entered '98.1'	System	14 Sep 2020 16:04:03
	System	14 Sep 2020 16:04:03



US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df' User entered 'No (N)'	System	14 Sep 2020 16:04:03
	System	14 Sep 2020 16:04:03

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:01:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '921380e1-637f-4785-adcc-348ee19ac4df' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 16:04:03
	System	14 Sep 2020 16:04:03

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8' User entered 'Yes (Y)'	System	16 Sep 2020 02:20:44
	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8' User entered '98.4'	System	16 Sep 2020 02:20:44
	System	16 Sep 2020 02:20:44

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8' User entered 'No (N)'	System	16 Sep 2020 02:20:44
	System	16 Sep 2020 02:20:44



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '50a6c3f7-e68e-440b-831e-1a21d74728a8' User entered '15 Sep 2020 22:20'	System	16 Sep 2020 02:20:44
	System	16 Sep 2020 02:20:44

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:30:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851' User entered 'Yes (Y)'	System	16 Sep 2020 17:31:12
	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851' User entered '98.4'	System	16 Sep 2020 17:31:12
	System	16 Sep 2020 17:31:12

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851' User entered 'No (N)'	System	16 Sep 2020 17:31:12
	System	16 Sep 2020 17:31:12

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e0825938-f403-4ffc-8876-a068d0794851' User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:12
	System	16 Sep 2020 17:31:12



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:11:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d' User entered 'Yes (Y)'	System	17 Sep 2020 16:14:25
	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d' User entered '98.4'	System	17 Sep 2020 16:14:25
	System	17 Sep 2020 16:14:25

US3022052

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d'	System	17 Sep 2020 16:14:25
User entered 'No (N)'	System	17 Sep 2020 16:14:25

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e837af60-a1d9-4f79-a067-f04be3927e9d' User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:25
	System	17 Sep 2020 16:14:25

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'None (1)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered 'No (N)'	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75' User entered 'No (N)'	System	11 Sep 2020 21:15:36
	System	11 Sep 2020 21:15:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75' User entered 'None (1)'	System	11 Sep 2020 21:15:36
	System	11 Sep 2020 21:15:36

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:15:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8305be49-e0ce-4a08-932a-d9f2d747fd75'	System	11 Sep 2020 21:15:36
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 21:15:36

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a' User entered 'No (N)'	System	12 Sep 2020 13:38:53
	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a' User entered 'No (N)'	System	12 Sep 2020 13:38:53
	System	12 Sep 2020 13:38:53

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a'	System	12 Sep 2020 13:38:53
User entered 'None (1)'	System	12 Sep 2020 13:38:53

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'a26a1578-e57b-47b5-a073-0d9fd8475c3a' User entered '12 Sep 2020 09:38'	System	12 Sep 2020 13:38:53
	System	12 Sep 2020 13:38:53

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f'	System	12 Sep 2020 16:08:08
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:22', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f' User entered 'No (N)'	System	12 Sep 2020 16:08:08
	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f' User entered 'No (N)'	System	12 Sep 2020 16:08:08
	System	12 Sep 2020 16:08:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f' User entered 'None (1)'	System	12 Sep 2020 16:08:08
	System	12 Sep 2020 16:08:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '32e7453a-6a6a-470a-b26f-34f604b80c9f' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:08:08
	System	12 Sep 2020 16:08:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:23', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9' User entered 'No (N)'	System	13 Sep 2020 16:03:06
	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9' User entered 'No (N)'	System	13 Sep 2020 16:03:06
	System	13 Sep 2020 16:03:06

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered 'None (1)'	System	13 Sep 2020 16:03:06

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '396fef49-ee08-418f-b42a-06e3f009fea9'	System	13 Sep 2020 16:03:06
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 16:03:06

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered 'None (1)'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered 'No (N)'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered 'No (N)'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered 'None (1)'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '548a936a-21f4-4a2b-b39d-f7bb2b7ba71c' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:02:23
	System	14 Sep 2020 16:02:23

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'None (1)'	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:49', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab' User entered 'No (N)'	System	16 Sep 2020 02:21:01
	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab' User entered 'No (N)'	System	16 Sep 2020 02:21:01
	System	16 Sep 2020 02:21:01

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered 'None (1)'	System	16 Sep 2020 02:21:01

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:20:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd92d22af-03aa-4ce7-bf8f-8e798431a4ab'	System	16 Sep 2020 02:21:01
User entered '15 Sep 2020 22:20'	System	16 Sep 2020 02:21:01

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'None (1)'	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6' User entered 'No (N)'	System	16 Sep 2020 17:31:23
	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6' User entered 'No (N)'	System	16 Sep 2020 17:31:23
	System	16 Sep 2020 17:31:23

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:16', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6'	System	16 Sep 2020 17:31:23
User entered 'None (1)'	System	16 Sep 2020 17:31:23

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:19', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '693045d0-b217-4b45-8344-599098309cb6' User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:23
	System	16 Sep 2020 17:31:23

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cadc979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'None (1)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cad979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'No (N)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cad979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'No (N)'	System	17 Sep 2020 16:14:36

US3022052

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cadc979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered 'None (1)'	System	17 Sep 2020 16:14:36

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5cadc979-8a04-4d5c-a632-6b74dfa28ff8'	System	17 Sep 2020 16:14:36
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:36

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'None (0)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:43', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered 'No (N)'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-11T17:10:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '6b99b667-3f57-4bb0-94d5-b42663337509' User entered '11 Sep 2020 17:10'	System	11 Sep 2020 21:10:51
	System	11 Sep 2020 21:10:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 17:06'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 19:36'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:38:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'None (0)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered 'No (N)'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T09:39:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '4133c784-8ac1-4597-b508-2a58ad244ace' User entered '12 Sep 2020 09:39'	System	12 Sep 2020 13:39:09
	System	12 Sep 2020 13:39:09

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '11 Sep 2020 20:31'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 2'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'None (0)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered 'No (N)'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-12T12:02:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c4834886-4a65-4085-b7b1-5ced8d70c5e6' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 16:08:52
	System	12 Sep 2020 16:08:52



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 3'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'None (0)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:02:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered 'No (N)'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-13T12:03:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b0649704-b9fa-4ff4-ad53-f609521bb47d' User entered '13 Sep 2020 12:03'	System	13 Sep 2020 16:03:20
	System	13 Sep 2020 16:03:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 4'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:46', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'None (0)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:52', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered 'No (N)'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-14T12:00:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd1d64f46-2df5-480e-9f27-e52626c98b0d' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:03:24
	System	14 Sep 2020 16:03:24

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 21:00:08



US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 5'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:03', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:09', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'None (0)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:15', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered 'No (N)'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-15T22:21:17', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '24d34b03-f000-4cfc-82e9-94ea47c53a71' User entered '15 Sep 2020 22:21'	System	16 Sep 2020 02:21:20
	System	16 Sep 2020 02:21:20

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 6'	System	11 Sep 2020 21:00:08

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:28', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'None (0)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered 'No (N)'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-16T13:31:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'efc3f19b-7c73-4d1a-a42b-a1963169da94' User entered '16 Sep 2020 13:31'	System	16 Sep 2020 17:31:40
	System	16 Sep 2020 17:31:40

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	11 Sep 2020 21:00:08
User entered 'Day 7'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:36', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:37', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:40', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:41', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'None (0)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

US3022052

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered 'No (N)'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-17T12:14:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'e4624a50-cf7e-4fb3-aea6-9dbc6bf501b8' User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:14:51
	System	17 Sep 2020 16:14:51

**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 21:00:08



**US3022052**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 21:00:08

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '21 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 17:42:20

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:42:20

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:42:25

**US3022052**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	22 Sep 2020 17:42:25

**US3022052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:35:17



**US3022052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:35:17

**US3022052**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:35:17

US3022052

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:35:17

**US3022052**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:35:22

**US3022052**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	25 Sep 2020 19:35:22

**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:33:46

**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 14:33:46

**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 14:33:46



**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:33:46

**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:33:51

**US3022052**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	08 Oct 2020 14:33:51

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:26

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:26

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[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 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:39:26

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'VISIT3'	System	15 Oct 2020 13:39:26

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:50



**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '10:15'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered '09 Oct 2020 10:15'	System	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '36.8' C	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '74'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'bpm'	System	15 Oct 2020 13:39:50



**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '16'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

US3022052

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'breaths/min'	System	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '113'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '75'	(b) (4), (b) (6)	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'mmHg'	System	15 Oct 2020 13:39:50

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10



**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:00

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:40:00

US3022052

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '09 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered '10:32'	(b) (4), (b) (6)	15 Oct 2020 13:40:12

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered '09 Oct 2020 10:32'	System	15 Oct 2020 13:40:12

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:40:17

**US3022052**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:10
User entered 'I'	System	15 Oct 2020 13:40:17



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 64'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

[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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:47', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered 'No (N)'	System	27 Sep 2020 12:42:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered 'No (N)'	System	27 Sep 2020 12:42:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-09-27T08:42:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '8e27c3fe-57b3-418a-b54c-4e5c8dfca952'	System	27 Sep 2020 12:42:58
User entered '27 Sep 2020 08:42:56'	System	27 Sep 2020 12:42:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 71'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

[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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848'	System	04 Oct 2020 11:22:36
User entered 'No (N)'	System	04 Oct 2020 11:22:36



US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848'	System	04 Oct 2020 11:22:36
User entered 'No (N)'	System	04 Oct 2020 11:22:36

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-04T07:22:34', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5bf5c427-84ec-4bb0-80ff-3dfdcfce1848' User entered '04 Oct 2020 07:22:34'	System	04 Oct 2020 11:22:36
	System	04 Oct 2020 11:22:36

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 78'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Please 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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Please 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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Please 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 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '11 Oct 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:28:31
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '15 Oct 2020 23:59'	System	28 Jul 2020 19:43:58



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 92'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:32', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered 'Yes (Y)'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:38', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069'	System	28 Oct 2020 22:00:27
User entered 'No (N)'	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

[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)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T17:59:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069'	System	28 Oct 2020 22:00:27
User entered 'No (N)'	System	28 Oct 2020 22:00:27

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T18:00:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069'	System	28 Oct 2020 22:00:27
User entered 'No (N)'	System	28 Oct 2020 22:00:27

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-10-28T18:00:24', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '3b762e49-f8cb-4964-9288-767c6d525069' User entered '28 Oct 2020 18:00:24'	System	28 Oct 2020 22:00:27
	System	28 Oct 2020 22:00:27

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 19:43:58



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 99'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

[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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:53', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840' User entered 'Yes (Y)'	System	04 Nov 2020 23:08:10
	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:48', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'No (N)'	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:45', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840' User entered 'No (N)'	System	04 Nov 2020 23:08:10
	System	04 Nov 2020 23:08:10

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:42', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'Yes (Y)'	System	04 Nov 2020 23:08:10

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Please 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)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840'	System	04 Nov 2020 23:08:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 23:08:10

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-04T18:07:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '1297865f-95a6-4b95-9802-752314a4a840' User entered '04 Nov 2020 18:07:59'	System	04 Nov 2020 23:08:10
	System	04 Nov 2020 23:08:10

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 19:43:58



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 106'	System	28 Jul 2020 19:43:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

[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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:44', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff' User entered 'No (N)'	System	10 Nov 2020 17:07:58
	System	10 Nov 2020 17:07:58

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:50', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff' User entered 'No (N)'	System	10 Nov 2020 17:07:58
	System	10 Nov 2020 17:07:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-10T12:07:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'd53fa099-f65c-4c0c-acdc-fa53818d38ff' User entered '10 Nov 2020 12:07:56'	System	10 Nov 2020 17:07:58
	System	10 Nov 2020 17:07:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered 'Day 113'	System	28 Jul 2020 19:43:58



US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:07', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664'	System	17 Nov 2020 17:45:17
User entered 'No (N)'	System	17 Nov 2020 17:45:17

US3022052

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:47

Have you been exposed to someone with 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 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:10', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664'	System	17 Nov 2020 17:45:17
User entered 'No (N)'	System	17 Nov 2020 17:45:17

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-17T12:45:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'aa80c738-3e7e-43a2-8e7c-10baa6252664' User entered '17 Nov 2020 12:45:14'	System	17 Nov 2020 17:45:17
	System	17 Nov 2020 17:45:17

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:35:16
Data entry locked.	System	28 Jul 2020 19:43:58
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 19:43:58

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-26T18:21:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '38ee87c6-201d-4a67-a3ce-f3a33a7cb8aa' User entered 'No (N)'	System	26 Nov 2020 23:21:27

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-26T18:21:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '38ee87c6-201d-4a67-a3ce-f3a33a7cb8aa' User entered 'No (N)'	System	26 Nov 2020 23:21:27

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-11-26T18:21:26', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '38ee87c6-201d-4a67-a3ce-f3a33a7cb8aa' User entered '26 Nov 2020 18:21:26'	System	26 Nov 2020 23:21:27
	System	26 Nov 2020 23:21:27

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:28:31

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

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**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-03T08:49:20', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '22196647-ee2b-41da-9aaa-a585e7c7ccb2'	System	03 Dec 2020 13:49:34
User entered 'No (N)'	System	03 Dec 2020 13:49:34



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-03T08:49:25', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '22196647-ee2b-41da-9aaa-a585e7c7ccb2'	System	03 Dec 2020 13:49:34
User entered 'No (N)'	System	03 Dec 2020 13:49:34

**US3022052**

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

**Form: Safety Follow Up Diary**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-03T08:49:31', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '22196647-ee2b-41da-9aaa-a585e7c7ccb2' User entered '03 Dec 2020 08:49:31'	System	03 Dec 2020 13:49:34
	System	03 Dec 2020 13:49:34

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-10T06:55:56', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '86bde4d5-c66d-4607-9370-62d04547fd08'	System	10 Dec 2020 11:56:07
User entered 'No (N)'	System	10 Dec 2020 11:56:07

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-10T06:55:59', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '86bde4d5-c66d-4607-9370-62d04547fd08'	System	10 Dec 2020 11:56:07
User entered 'No (N)'	System	10 Dec 2020 11:56:07

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-10T06:56:04', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '86bde4d5-c66d-4607-9370-62d04547fd08' User entered '10 Dec 2020 06:56:04'	System	10 Dec 2020 11:56:07
	System	10 Dec 2020 11:56:07



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-19T12:00:55', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7416d08c-a0e6-4f01-9cd0-51656135e101' User entered 'No (N)'	System	19 Dec 2020 17:01:08
	System	19 Dec 2020 17:01:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-19T12:00:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7416d08c-a0e6-4f01-9cd0-51656135e101'	System	19 Dec 2020 17:01:08
User entered 'No (N)'	System	19 Dec 2020 17:01:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2020-12-19T12:01:02', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '7416d08c-a0e6-4f01-9cd0-51656135e101' User entered '19 Dec 2020 12:01:02'	System	19 Dec 2020 17:01:08
	System	19 Dec 2020 17:01:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-02T12:13:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '08e14444-4ac0-4e91-910e-e888df053d10' User entered 'No (N)'	System	02 Jan 2021 17:14:06
	System	02 Jan 2021 17:14:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-02T12:14:01', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '08e14444-4ac0-4e91-910e-e888df053d10'	System	02 Jan 2021 17:14:06
User entered 'No (N)'	System	02 Jan 2021 17:14:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-02T12:14:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '08e14444-4ac0-4e91-910e-e888df053d10' User entered '02 Jan 2021 12:14:05'	System	02 Jan 2021 17:14:06
	System	02 Jan 2021 17:14:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-09T14:51:51', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '724c12fc-cba3-428b-a041-84328e42ef6a' User entered 'No (N)'	System	09 Jan 2021 19:52:01
	System	09 Jan 2021 19:52:01

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-09T14:51:54', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '724c12fc-cba3-428b-a041-84328e42ef6a' User entered 'No (N)'	System	09 Jan 2021 19:52:01

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-09T14:51:58', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '724c12fc-cba3-428b-a041-84328e42ef6a' User entered '09 Jan 2021 14:51:58'	System	09 Jan 2021 19:52:01
	System	09 Jan 2021 19:52:01

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-14T06:46:57', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '641c255d-8d83-46cf-bbfa-30bb3109b3ec' User entered 'No (N)'	System	14 Jan 2021 11:47:08
	System	14 Jan 2021 11:47:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-14T06:47:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '641c255d-8d83-46cf-bbfa-30bb3109b3ec'	System	14 Jan 2021 11:47:08
User entered 'No (N)'	System	14 Jan 2021 11:47:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-14T06:47:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '641c255d-8d83-46cf-bbfa-30bb3109b3ec' User entered '14 Jan 2021 06:47:05'	System	14 Jan 2021 11:47:08
	System	14 Jan 2021 11:47:08

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-21T06:52:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c424b04a-11d6-49f8-8f87-86ce58c4c381' User entered 'No (N)'	System	21 Jan 2021 11:52:40
	System	21 Jan 2021 11:52:40

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-21T06:52:30', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c424b04a-11d6-49f8-8f87-86ce58c4c381' User entered 'No (N)'	System	21 Jan 2021 11:52:40
	System	21 Jan 2021 11:52:40



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-21T06:52:35', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'c424b04a-11d6-49f8-8f87-86ce58c4c381' User entered '21 Jan 2021 06:52:35'	System	21 Jan 2021 11:52:40
	System	21 Jan 2021 11:52:40

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-28T06:54:27', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b56b05af-6348-4779-8e75-90ce7617fbaf' User entered 'No (N)'	System	28 Jan 2021 11:54:37
	System	28 Jan 2021 11:54:37

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-28T06:54:29', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b56b05af-6348-4779-8e75-90ce7617fbaf' User entered 'No (N)'	System	28 Jan 2021 11:54:37

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-01-28T06:54:33', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'b56b05af-6348-4779-8e75-90ce7617fbaf' User entered '28 Jan 2021 06:54:33'	System	28 Jan 2021 11:54:37
	System	28 Jan 2021 11:54:37

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-04T07:11:05', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ce08135f-f4dd-4afa-b862-b8a4c4b1d15b' User entered 'No (N)'	System	04 Feb 2021 12:11:15
	System	04 Feb 2021 12:11:15

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-04T07:11:08', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ce08135f-f4dd-4afa-b862-b8a4c4b1d15b'	System	04 Feb 2021 12:11:15
User entered 'No (N)'	System	04 Feb 2021 12:11:15

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-04T07:11:12', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'ce08135f-f4dd-4afa-b862-b8a4c4b1d15b'	System	04 Feb 2021 12:11:15
User entered '04 Feb 2021 07:11:12'	System	04 Feb 2021 12:11:15

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-13T13:01:11', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '738d1ccb-eac3-4d08-972b-121b35b1277b' User entered 'No (N)'	System	13 Feb 2021 18:03:39
	System	13 Feb 2021 18:03:39

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-13T13:01:14', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '738d1ccb-eac3-4d08-972b-121b35b1277b'	System	13 Feb 2021 18:03:39
User entered 'No (N)'	System	13 Feb 2021 18:03:39

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-13T13:01:18', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '738d1ccb-eac3-4d08-972b-121b35b1277b' User entered '13 Feb 2021 13:01:18'	System	13 Feb 2021 18:03:39

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-25T06:27:54-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '48767f6d-0d6c-4406-afa8-94f3a0959cec' User entered 'No (N)'	System	25 Feb 2021 11:28:07
	System	25 Feb 2021 11:28:07

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-25T06:28:00-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '48767f6d-0d6c-4406-afa8-94f3a0959cec'	System	25 Feb 2021 11:28:07
User entered 'No (N)'	System	25 Feb 2021 11:28:07

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-02-25T06:28:04-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '48767f6d-0d6c-4406-afa8-94f3a0959cec' User entered '25 Feb 2021 11:28:04'	System	25 Feb 2021 11:28:07
	System	25 Feb 2021 11:28:07

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-06T12:48:42-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '88c74ee1-5901-4db2-8e3d-222838d6ae5a' User entered 'No (N)'	System	06 Mar 2021 17:48:54
	System	06 Mar 2021 17:48:54



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-06T12:48:45-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '88c74ee1-5901-4db2-8e3d-222838d6ae5a'	System	06 Mar 2021 17:48:54
User entered 'No (N)'	System	06 Mar 2021 17:48:54

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-06T12:48:49-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '88c74ee1-5901-4db2-8e3d-222838d6ae5a' User entered '06 Mar 2021 12:48:49'	System	06 Mar 2021 17:48:54
	System	06 Mar 2021 17:48:54

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-11T11:25:26-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '690ac021-f174-4564-b887-7a5950923f9c'	System	11 Mar 2021 16:25:40
User entered 'No (N)'	System	11 Mar 2021 16:25:40

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-11T11:25:28-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '690ac021-f174-4564-b887-7a5950923f9c'	System	11 Mar 2021 16:25:40
User entered 'No (N)'	System	11 Mar 2021 16:25:40

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-11T11:25:31-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '690ac021-f174-4564-b887-7a5950923f9c' User entered '11 Mar 2021 11:25:31'	System	11 Mar 2021 16:25:40
	System	11 Mar 2021 16:25:40



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-20T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '40f0a3a2-cdd9-426d-9136-cf3aa92b3c05'	System	20 Mar 2021 16:01:06
User entered 'No (N)'	System	20 Mar 2021 16:01:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-20T12:00:32-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '40f0a3a2-cdd9-426d-9136-cf3aa92b3c05'	System	20 Mar 2021 16:01:06
User entered 'No (N)'	System	20 Mar 2021 16:01:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-20T12:00:35-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '40f0a3a2-cdd9-426d-9136-cf3aa92b3c05' User entered '20 Mar 2021 12:00:35'	System	20 Mar 2021 16:01:06
	System	20 Mar 2021 16:01:06

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-27T12:33:10-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'f3e192f5-5bed-47b1-97b5-da351ace6384'	System	27 Mar 2021 16:33:19
User entered 'No (N)'	System	27 Mar 2021 16:33:19

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-27T12:33:12-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'f3e192f5-5bed-47b1-97b5-da351ace6384'	System	27 Mar 2021 16:33:19
User entered 'No (N)'	System	27 Mar 2021 16:33:19

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-27T12:33:16-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: 'f3e192f5-5bed-47b1-97b5-da351ace6384'	System	27 Mar 2021 16:33:19
User entered '27 Mar 2021 12:33:16'	System	27 Mar 2021 16:33:19

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-03T18:01:14-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '15f01ac9-5313-4bf4-9229-3438947a69d8' User entered 'No (N)'	System	03 Apr 2021 22:04:42
	System	03 Apr 2021 22:04:42



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-03T18:01:17-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '15f01ac9-5313-4bf4-9229-3438947a69d8' User entered 'No (N)'	System	03 Apr 2021 22:04:42
	System	03 Apr 2021 22:04:42

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-03T18:01:20-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '15f01ac9-5313-4bf4-9229-3438947a69d8'	System	03 Apr 2021 22:04:42
User entered '03 Apr 2021 18:01:20'	System	03 Apr 2021 22:04:42

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-08T07:20:21-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5c9b3cd3-4769-4c3d-a9be-574dbe07b087'	System	18 Apr 2021 21:59:21
User entered 'No (N)'	System	18 Apr 2021 21:59:21

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-08T07:20:24-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5c9b3cd3-4769-4c3d-a9be-574dbe07b087'	System	18 Apr 2021 21:59:21
User entered 'No (N)'	System	18 Apr 2021 21:59:21

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-08T07:20:27-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '5c9b3cd3-4769-4c3d-a9be-574dbe07b087' User entered '08 Apr 2021 07:20:27'	System	18 Apr 2021 21:59:21
	System	18 Apr 2021 21:59:21



**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-18T17:59:19-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '239f43e1-55d9-4dd1-a538-8cd7b4289c97'	System	18 Apr 2021 21:59:27
User entered 'No (N)'	System	18 Apr 2021 21:59:27

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-18T17:59:22-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '239f43e1-55d9-4dd1-a538-8cd7b4289c97'	System	18 Apr 2021 21:59:27
User entered 'No (N)'	System	18 Apr 2021 21:59:27

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-18T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '239f43e1-55d9-4dd1-a538-8cd7b4289c97'	System	18 Apr 2021 21:59:27
User entered '18 Apr 2021 17:59:25'	System	18 Apr 2021 21:59:27

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-25T18:46:08-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '795b112a-ea87-4d37-af0f-11398efac502'	System	25 Apr 2021 22:46:16
User entered 'No (N)'	System	25 Apr 2021 22:46:16

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-25T18:46:10-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '795b112a-ea87-4d37-af0f-11398efac502'	System	25 Apr 2021 22:46:16
User entered 'No (N)'	System	25 Apr 2021 22:46:16

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-25T18:46:14-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '795b112a-ea87-4d37-af0f-11398efac502'	System	25 Apr 2021 22:46:16
User entered '25 Apr 2021 18:46:14'	System	25 Apr 2021 22:46:16

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-29T06:59:34-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '49cedac3-1d81-4196-9b1b-b2093879d7e1' User entered 'No (N)'	System	29 Apr 2021 10:59:41



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Have you been exposed to someone with 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 (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-29T06:59:35-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '49cedac3-1d81-4196-9b1b-b2093879d7e1' User entered 'No (N)'	System	29 Apr 2021 10:59:41

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-04-29T06:59:38-04:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '49cedac3-1d81-4196-9b1b-b2093879d7e1' User entered '29 Apr 2021 06:59:38'	System	29 Apr 2021 10:59:41
	System	29 Apr 2021 10:59:41

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:28:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:28:31



**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:28:31

**US3022052**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:28:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:28:31

US3022052

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:50:47**

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 08:37:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-06T12:48:56-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '21c69e8c-cd42-4f4d-82c3-b082faffc739'	System	06 Mar 2021 17:49:08
User entered 'No (N)'	System	06 Mar 2021 17:49:08

**US3022052**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:37:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2C7AC11F-0F49-4951-8065-E4219BCEBE75)', Time: '2021-03-06T12:49:03-05:00', User OID: 'PatientReportedOutcome (US3022052)', ODM File OID: '21c69e8c-cd42-4f4d-82c3-b082faffc739'	System	06 Mar 2021 17:49:08
User entered '06 Mar 2021 12:49:03'	System	06 Mar 2021 17:49:08

**US3022052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 22:51:22

**US3022052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:51:22

**US3022052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 22:51:22

**US3022052**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:51:22



US3022052

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 22:51:27

**US3022052**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:49:09
User entered 'I'	System	13 Nov 2020 22:51:27

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 13:24:34

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '09 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 13:24:34

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Dec 2020 13:24:34

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 13:24:34

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 13:24:48

**US3022052**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User entered 'I'	System	10 Dec 2020 13:24:48



**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 16:43:50

**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '07 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 16:43:50

**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Jan 2021 16:43:50

**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:43:50

**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 16:44:22

**US3022052**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User entered 'I'	System	07 Jan 2021 16:44:22

**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:11

**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 13:38:11



**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:11

**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 13:38:11

**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:22

**US3022052**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:42:26
User entered 'I'	System	01 Mar 2021 13:38:22

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 13:39:03

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:39:03

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[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 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:39:03

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered 'VISIT4'	System	01 Mar 2021 13:39:03



US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'No (N)'	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered empty.	System	30 Mar 2021 16:17:44

US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44



**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered empty.	System	30 Mar 2021 16:17:44

US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered empty.	System	30 Mar 2021 16:17:44

US3022052

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered empty.	System	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered empty.	System	30 Mar 2021 16:17:44

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15



**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 13:39:53

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '24 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 13:39:53

US3022052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 13:40:36

US3022052

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '24 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 13:40:36

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '09:53'	(b) (4), (b) (6)	01 Mar 2021 13:40:36

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered '24 Feb 2021 09:53'	System	01 Mar 2021 13:40:36

**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 13:40:56



**US3022052**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:56:15
User entered 'I'	System	01 Mar 2021 13:40:56

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:05:32

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:05:32

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:05:32

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:05:32

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:05:36

**US3022052**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 18:05:36

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:41



**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:41:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User entered 'UNBLND_DECIDE'	System	24 Mar 2021 17:41:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41



**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:42:41

US3022052

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4)	24 Mar 2021 17:44:45
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	24 Mar 2021 17:44:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 17:44:45
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	24 Mar 2021 17:42:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User entered empty.	System	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:47**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User entered empty.	System	24 Mar 2021 17:42:41

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:45:52

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 17:45:52



**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '08:20'	(b) (4), (b) (6)	24 Mar 2021 17:45:52

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User entered '24 Mar 2021 08:20'	System	24 Mar 2021 17:45:52

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:46:34

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 17:46:34

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '08:29'	(b) (4), (b) (6)	24 Mar 2021 17:46:34

**US3022052**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:23
User entered '24 Mar 2021 08:29'	System	24 Mar 2021 17:46:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:50:47**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	11 Nov 2020 15:04:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:20:12
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:36:27

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:35
User entered 'USA-US051-2020-mRNA-1273-P301000010'	System	06 Nov 2020 16:48:27
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 16:48:27



US3022052

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Oesophageal neoplasms malignant, PT: Oesophageal carcinoma, LLT: Esophageal cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:22:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:22:23
Data point term sent to Coder	System	05 Nov 2020 16:21:48
User entered 'Esophageal Cancer'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: please confirm, did event of "esophageal cancer" start on 15 Oct 2020? ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:45:33
Query 'PV Query: please confirm, did event of "esophageal cancer" start on 15 Oct 2020? ' answered with 'Yes, as this was the day of his biopsy' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:14:51
User opened query 'PV Query: please confirm, did event of "esophageal cancer" start on 15 Oct 2020? ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:43:17
User closed query 'PV Query: Please clarify event onset date; reported as 09 Nov 2020 per paper SAE form and 15 Oct 2020 in the EDC. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:39:45
Query 'PV Query: Please clarify event onset date; reported as 09 Nov 2020 per paper SAE form and 15 Oct 2020 in the EDC. ' answered with 'This date is correct ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:47:43
User opened query 'PV Query: Please clarify event onset date; reported as 09 Nov 2020 per paper SAE form and 15 Oct 2020 in the EDC. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:27:36
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '15 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 14:45:46
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'As of today there is no end date available' (Site from Safety).	Chevon Roberts (b) (4) (b) (4)	12 Apr 2021 20:15:13
User closed query 'PV Query: Please clarify event end date/outcome for event esophageal cancer. Per paper SAE form, end date reported as 15 Nov 2020 and outcome is reported as resolving, and per EDC, outcome is not resolved. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:39:48
Query 'PV Query: Please clarify event end date/outcome for event esophageal cancer. Per paper SAE form, end date reported as 15 Nov 2020 and outcome is reported as resolving, and per EDC, outcome is not resolved. ' answered with 'Esophageal cancer has not resolved ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:48:06
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:28:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:28:15
User opened query 'PV Query: Please clarify event end date/outcome for event esophageal cancer. Per paper SAE form, end date reported as 15 Nov 2020 and outcome is reported as resolving, and per EDC, outcome is not resolved. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:27:01
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' answered with 'is this is technically not resolved does this need to be end dated?' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:11:50
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 16:59:49
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:56:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'This is still ongoing.' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	29 Jan 2021 19:43:37
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 10:21:04
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:25:08
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'NO END DATE TO PROVIDE AT THIS MOMENT ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:12:23
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:10:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:01:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'There is no end date for this as of yet.' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:30:24
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:20:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:12
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'will do' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 13:14:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:37:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:35
Query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' answered with 'The subject wasn't admitted ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:14:40
User opened query 'PV Query: If the subject was admitted to the hospital overnight, please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:38:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query 'PV Query: please confirm if subject was hospitalized for event "esophageal cancer" ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:07:18
Query 'PV Query: please confirm if subject was hospitalized for event "esophageal cancer" ' answered with 'Subject was hospitalized but not until 09Nov2021 for the surgical remover of the cancer.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 21:02:48
User opened query 'PV Query: please confirm if subject was hospitalized for event "esophageal cancer" ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 12:43:03
User closed query 'PV Query: Please confirm if the subject was hospitalized for the event. Per paper SAE form, hospitalization occurred from 09 Nov 2020 through 15 Nov 2020 after esophagectomy and gastrostomy tube placement. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:39:50
Query 'PV Query: Please confirm if the subject was hospitalized for the event. Per paper SAE form, hospitalization occurred from 09 Nov 2020 through 15 Nov 2020 after esophagectomy and gastrostomy tube placement. ' answered with 'subject was hospitalized' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:45:14
User opened query 'PV Query: Please confirm if the subject was hospitalized for the event. Per paper SAE form, hospitalization occurred from 09 Nov 2020 through 15 Nov 2020 after esophagectomy and gastrostomy tube placement. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:27:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 10:27:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 01:59:56
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'subject wasn't hospitalized. PI wanted to submitted as an SAE due to Cancer diagnosis ' (Site from System).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 13:18:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Un-verified.	System	13 Nov 2020 13:15:30
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:07:39
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 16:22:56
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	05 Nov 2020 16:22:56
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	05 Nov 2020 16:21:44
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).	System	05 Nov 2020 16:21:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 16:21:44
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:21:44
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	05 Nov 2020 16:21:09
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:47

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:03
User closed query 'Please confirm patient was hospitalized - per source no.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:00:00
Query 'Please confirm patient was hospitalized - per source no.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:17:24
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
	(b) (4), (b) (6)	11 Nov 2020 15:05:39
User opened query 'Please confirm patient was hospitalized - per source no.' (Site from CRA).		
User entered '15 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	05 Nov 2020 16:22:56
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:10:54
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:06
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'subject wasn't hospitalized. PI wanted to submitted as an SAE due to Cancer diagnosis ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:05
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 13:15:30
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:38:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:37:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:37:42
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:22:56
	(b) (4)	
	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	



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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'I'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Please confirm. Per source not applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:03
Query 'Please confirm. Per source not applicable.' answered with 'this is correct' (Site from CRA). DataPoint Verified.	Shanice Bennett (b) (4)	13 Nov 2020 13:16:57
	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:07:39
	(b) (4), (b) (6)	11 Nov 2020 15:06:44
User opened query 'Please confirm. Per source not applicable.' (Site from CRA).		
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 16:38:59
User entered '1'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 16:38:59
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09



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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:00:17
DataPoint Un-verified.	Shanice Bennett (b) (4)	13 Nov 2020 13:15:52
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Shanice Bennett (b) (4)	13 Nov 2020 13:15:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered '0'	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Nov 2020 12:11:21
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:01:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'this event on going which needs to be not recovered/not resolved' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:32:41
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:20:24
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:13:38
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 13:16:33
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:37:20
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User entered empty.	Shanice Bennett (b) (4)	05 Nov 2020 16:21:09
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CLR re-query: Response noted; however esophagectomy is not recorded in concomitant procedure. please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:52:52
Query 'Per CDM CLR re-query: Response noted; however esophagectomy is not recorded in concomitant procedure. please review and update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 15:41:14
User opened query 'Per CDM CLR re-query: Response noted; however esophagectomy is not recorded in concomitant procedure. please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:34:10
User closed query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:28:17
Query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' answered with 'Yes this updated on the con proc page' (Site from DM).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:35:14
User opened query 'Per CDM, per DM CLR re-query: Thank you for updating the Con Proc page. Please note that Esophagectomy has not been recorded. Kindly update as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:40
User closed query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:45:40

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 20:39:56
User opened query 'Per DM CLR: Narrative indicates that the subject had endoscopy, esophageal tissue biopsy, Esophagectomy and Gastrostomy Tube inserted for feeding. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:18:49
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:11:34
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)	16 Nov 2020 16:11:27
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 'no COVID-19 test was done' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:16:23
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medication was added ' (Site from Safety).	Shanice Bennett (b) (4)	13 Nov 2020 13:16:09

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EAB) (1725)

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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)	12 Nov 2020 14:36:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 14:36:38
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:39
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:21:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 16:21:44
User entered 'Subject reported on day 85 safety phone call that he was diagnosed with esophageal cancer and has an upcoming surgery. Called and followed with patient. He reports over the past 3 years he has had difficulty in swallowing. He states he previously never sought care for this treated self for what he thought was acid reflux. Subject reports he had an endoscope on 15OCT2020 and had an esophageal tissue biopsied. He received the results of esophageal cancer and has surgery scheduled for 09Nov2020 for an esophagectomy and gastrostomy tube placed for feeding. He denies chemo or radiation planned at this time.' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:44
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:21:09
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Nov 2020 16:21:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:21:09

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 16:21:09



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 16:21:09

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:22
User entered	(b) (4), (b) (6)	25 Feb 2021 18:27:19
'USA-US051-2020-mRNA-1273-P301000010'		

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Oesophageal ulcers and perforation, PT: Oesophageal rupture, LLT: Esophageal tear - version MedDRA\\23.0.	Coder Import (b) (4)	25 Feb 2021 15:05:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 15:04:47
User entered 'Esophageal tear'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '15 Oct 2020'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	



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**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:04:36

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**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '18 Oct 2020'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:04:36

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Grade 4 (Grade 4)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	



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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'I'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '15 Oct 2020'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '18 Oct 2020'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

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**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	



US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Related (NOT RELATED)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Related (NOT RELATED)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 15:39:38
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 13:48:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 13:48:34
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 21:28:52
User entered 'None (NONE)'	Chevon Roberts (b) (4) (b) (4)	25 Feb 2021 15:04:36

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Un-verified.	System	12 Apr 2021 20:19:07
	Chevon Roberts (b) (4)	12 Apr 2021 20:19:07
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Chevon Roberts (b) (4)	12 Apr 2021 20:19:07
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	System	12 Apr 2021 20:18:25
	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Feb 2021 15:08:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Feb 2021 15:04:36
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 23:48:07
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated' (Site from DM).	Chevon Roberts (b) (4)	12 Apr 2021 20:19:38
DataPoint Un-verified.	Chevon Roberts (b) (4)	12 Apr 2021 20:18:25
User entered '0' reason for change: Data Entry Error	Chevon Roberts (b) (4)	12 Apr 2021 20:18:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:35:15
User entered '1' reason for change: Data Entry Error	Chevon Roberts (b) (4)	25 Feb 2021 15:08:09
User entered '0'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	



US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36
	(b) (4)	

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = COMPLICATION OF THE ESOPHAGEAL BIOPSY REQUIRING EMERGENCY SURGERY AND HOSPITAL ADMISSION. However, ESOPHAGEAL BIOPSY was done on 09NOV2020. How can this AE be a complication of the corresponding procedure if the procedure was done after the stop date of this AE. Review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:53:34
Query 'Per DM CLR: Narrative = COMPLICATION OF THE ESOPHAGEAL BIOPSY REQUIRING EMERGENCY SURGERY AND HOSPITAL ADMISSION. However, ESOPHAGEAL BIOPSY was done on 09NOV2020. How can this AE be a complication of the corresponding procedure if the procedure was done after the stop date of this AE. Review and reconcile data as appropriate. ' answered with 'after speaking with the subject, he was told the tear was from the biopsy that was done. He was just seen in October for it' (Site from DM). DataPoint Verified.	Chevon Roberts (b) (4) (b) (4)	20 Apr 2021 19:50:17
	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User opened query 'Per DM CLR: Narrative = COMPLICATION OF THE ESOPHAGEAL BIOPSY REQUIRING EMERGENCY SURGERY AND HOSPITAL ADMISSION. However, ESOPHAGEAL BIOPSY was done on 09NOV2020. How can this AE be a complication of the corresponding procedure if the procedure was done after the stop date of this AE. Review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:35:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 15:08:09
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 15:08:09

US3022052

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'This report was initially reported as esophageal cancer. after further review with the subject, the SAE was not related to the diagnosis of esophageal cancer but rather a complication of the esophageal biopsy requiring emergency surgery and hospital admission.' reason for change: Data Entry Error	Chevon Roberts (b) (4)	25 Feb 2021 15:08:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 15:04:36
User entered empty.	Chevon Roberts (b) (4)	25 Feb 2021 15:04:36

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 15:04:36

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 15:04:36

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 15:04:36

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:09:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:09:37
	(b) (4)	
Data point term sent to Coder	System	09 Apr 2021 17:55:18
User entered 'barretts esophgeus'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34



**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	23 Apr 2021 13:38:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 17:54:34
User entered 'un Aug 2020' (non-conformant).	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34



**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34



**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34



**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Apr 2021 17:54:34

US3022052

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:35:18
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 17:54:34

**US3022052**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 17:54:34



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:50:47

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:07:53
User closed query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:49:06
Query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 13:41:40
User opened query 'Per CDM: Per Diary Dose 2 (Temperature day), subject reports taking medication to treat pain/fever. Please confirm the medication details and record on the concomitant medication pages. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 20:45:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 12:11:33
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:36:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:14:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:14:44
Data point term sent to Coder	System	02 Oct 2020 12:13:25
User entered 'metformin'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'type 2 diabetes'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '1000'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:12:30



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:12:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:12:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:40:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:40:44
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 12:13:25
User entered 'junuvia'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'type 2 diabetes'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '100'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:15:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:15:45
Data point term sent to Coder	System	02 Oct 2020 12:14:27
User entered 'lisinopril'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hypertension'	(b) (4), (b) (6)	02 Oct 2020 12:13:30



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '10'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2017'	(b) (4), (b) (6)	02 Oct 2020 12:13:30



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:30

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:30

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 12:15:45
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Oct 2020 12:15:45
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	02 Oct 2020 12:14:27
User entered 'rosuvastatin'	(b) (4), (b) (6)	02 Oct 2020 12:13:56



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hyperlipidemia'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '10'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2013'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:13:56

US3022052

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 12:13:56



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 12:13:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:16:46
Data point term sent to Coder	System	02 Oct 2020 12:15:31
User entered 'levothyroxin'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'hypothyroidism'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '50'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'ug (ug)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'un UNK 2014'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 12:14:31



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User entered 'I'	System	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User entered 'I'	System	02 Oct 2020 12:14:31

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 09:56:44
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:27
User entered '804 (804)'	System	02 Oct 2020 12:14:31

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	11 Nov 2020 15:34:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 13:40:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Oct 2020 13:40:28
Data point term sent to Coder	System	15 Oct 2020 13:39:55
User entered 'IBUPROFEN'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:07:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'no maae or sae ' (Site from DM).	Shanice Bennett (b) (4)	05 Nov 2020 16:30:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:05:51
User entered 'PAIN AT INJECTION SITE'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '200'	(b) (4), (b) (6)	15 Oct 2020 13:39:10



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '13 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 13:39:10



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '13 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User entered empty.	System	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User entered empty.	System	15 Oct 2020 13:39:10

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:30
User entered empty.	System	15 Oct 2020 13:39:10

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 14:02:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 14:02:30
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 14:01:30
User entered 'Influenza VACCINE'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04
	(b) (4)	

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'PROPHYLAXIS'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0.5'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mL (mL)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User entered empty.	System	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User entered empty.	System	10 Nov 2020 14:01:04

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:34
User entered empty.	System	10 Nov 2020 14:01:04



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:03:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 14:03:30
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 14:02:31
User entered 'PNEUMOCOCCAL VACCINE'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	11 Nov 2020 15:34:54
User entered 'PROPHYLAXIS'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0.5'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mL (mL)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once (ONCE)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55
	(b) (4)	

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '26 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User entered empty.	System	10 Nov 2020 14:01:55



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User entered empty.	System	10 Nov 2020 14:01:55

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:56:41
User entered empty.	System	10 Nov 2020 14:01:55

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 17:03:38
Data point term sent to Coder	System	10 Nov 2020 16:38:19
User entered 'lansoprazole'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'esophageal Cancer'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '30'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '02 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:06

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:38:06

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Per DM CLR: Please review the medication name recorded as this does not match the succeeding data. Please correct or provide explanation for alternate use. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:10:39
Query 'Per DM CLR: Please review the medication name recorded as this does not match the succeeding data. Please correct or provide explanation for alternate use. Update as appropriate. ' answered with 'this is correct' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:27:40
User opened query 'Per DM CLR: Please review the medication name recorded as this does not match the succeeding data. Please correct or provide explanation for alternate use. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:21:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:22:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:22:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:54
Data point term sent to Coder	System	10 Nov 2020 16:39:21
User entered 'Reglin'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'esophageal cancer'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '40'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '02 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:34:54
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:38:34

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:38:34

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 10:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Dec 2020 10:13:36
Data point term sent to Coder	System	10 Dec 2020 13:24:46
User entered 'pantoprazole'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'esophageal cancer'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '40'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 13:24:19



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '15 Oct 2020'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 13:24:19

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 13:24:19

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 13:24:19

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 13:24:19

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 13:24:19



US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:19:42
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:12
Data point term sent to Coder	System	12 Apr 2021 18:20:10
User entered 'Amoxicillin/Cavulanate'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'Esophageal Tear'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered '875/125'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:19:56



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered '19 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered '25 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:37:12
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User entered '2'	System	12 Apr 2021 18:19:56



**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User entered '1'	System	12 Apr 2021 18:19:56

**US3022052**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:50:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:41:12
User entered '804 (804)'	System	12 Apr 2021 18:19:56

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:50:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:37:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please verify as AE notes concomitant procedure performed' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:12:14
Query 'Please verify as AE notes concomitant procedure performed' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	19 Nov 2020 20:41:14
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 20:38:48
	(b) (4)	
User opened query 'Please verify as AE notes concomitant procedure performed' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:00:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:38:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:37:43
User entered 'No (N)'	Shanice Bennett (b) (4)	01 Sep 2020 12:36:44
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:18:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 16:36:46
	(b) (4)	

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered 'gastrostomy tube'	Shanice Bennett (b) (4)	20 Nov 2020 16:36:46
	(b) (4)	

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	20 Nov 2020 16:36:46
	(b) (4)	

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 16:36:46
	(b) (4)	

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '09 Nov 2020'	(b) (4), (b) (6)	01 Mar 2021 15:39:34



US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'esophagectomy'	(b) (4), (b) (6)	01 Mar 2021 15:39:34

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Mar 2021 15:39:34

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:39:34

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '10 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 15:40:14

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'gastrostomy tube removed'	(b) (4), (b) (6)	01 Mar 2021 15:40:14

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	01 Mar 2021 15:40:14

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:41:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:40:14

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:58
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:25:31



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:58
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Esophageal Stent Placement'	(b) (4), (b) (6)	12 Apr 2021 18:25:31

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:58
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:28:13
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:25:31
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:25:31

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:58
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:28:13
User entered 'Esophageal Tear'	(b) (4), (b) (6)	12 Apr 2021 18:25:31

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:02
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:27:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:02
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Esophagogastro-duodenoscopy'	(b) (4), (b) (6)	12 Apr 2021 18:27:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:02
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:28:01
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:27:28
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:27:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:02
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:28:01
User entered 'Esophageal tear'	(b) (4), (b) (6)	12 Apr 2021 18:27:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:04
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:29:39



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:04
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Chest Tube Placement'	(b) (4), (b) (6)	12 Apr 2021 18:29:39

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:04
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:29:39

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:04
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:29:39

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:31:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Bronchoscopy'	(b) (4), (b) (6)	12 Apr 2021 18:31:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:31:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:31:28

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:33:36



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Right thoracoscopic evacuation pleural effusion'	(b) (4), (b) (6)	12 Apr 2021 18:33:36

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:33:36

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:27:12
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:33:36

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 14:50:47**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:30
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:36:20

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:30
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Mediastinal Drainage'	(b) (4), (b) (6)	12 Apr 2021 18:36:20

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:30
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:36:20

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:30
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:36:20

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:37
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	12 Apr 2021 18:37:00



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:37
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Thoracic Cavity Field Block'	(b) (4), (b) (6)	12 Apr 2021 18:37:00

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:37
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:37:00

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:37
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:37:00

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:41
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:56:43
User entered '15 Aug 2020'	(b) (4), (b) (6)	12 Apr 2021 18:39:39

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:41
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Esophagogastro-duodenoscopy'	(b) (4), (b) (6)	12 Apr 2021 18:39:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:50:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:41
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:39:39

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:41
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:39:39

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:50:47

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:48
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Apr 2021 19:01:33
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:01:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Apr 2021 18:40:26
User entered 'un Aug 2020' (non-conformant).	(b) (4), (b) (6)	12 Apr 2021 18:40:26



US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:50:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:48
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Esophageal Tissue Biopsy'	(b) (4), (b) (6)	12 Apr 2021 18:40:26

**US3022052**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 14:50:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:48
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Apr 2021 18:40:26

US3022052

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 14:50:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:48
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
DataPoint Verified.	(b) (4)	12 Apr 2021 19:41:40
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 18:40:26

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	System	13 Nov 2020 13:15:30
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered '06/Nov/2020 16:49'	System	06 Nov 2020 16:49:04

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:47

**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 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered '11/Nov/2020 15:03'	System	11 Nov 2020 15:03:39

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:47

**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 15:44:56
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 15:03:39

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
	(b) (4)	
Un-reviewed for Safety.	System	13 Nov 2020 13:15:30
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered '16/Nov/2020 16:14'	(b) (4) System	16 Nov 2020 16:14:15



US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:47

**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)	25 Feb 2021 18:28:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 16:14:15

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '25/Feb/2021 18:28'	(b) (4) System	25 Feb 2021 18:28:48

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:50:47

**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)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:57:22
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 18:28:48

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
	(b) (4)	
Un-reviewed for Safety.	System	13 Nov 2020 13:15:30
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '01/Mar/2021 09:57'	(b) (4) System	01 Mar 2021 14:57:35

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:50:47

**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)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 15:12:26
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 14:57:35

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
	(b) (4)	
Un-reviewed for Safety.	System	13 Nov 2020 13:15:30
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered '02/Mar/2021 09:13'	(b) (4) System	02 Mar 2021 15:13:17

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:50:47

**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)	22 Mar 2021 15:40:07
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 15:13:17

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	System	13 Nov 2020 13:15:30
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:56
User entered '22/Mar/2021 10:40'	(b) (4) System	22 Mar 2021 15:40:20



US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:50:47

**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)	25 Mar 2021 23:00:56
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 15:40:20

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'USA-US051-2020-MRNA-1273-P301000010'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:50:19
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:55:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:28:37
Un-reviewed for Safety.	System	25 Feb 2021 18:27:19
DataPoint Un-verified.	System	25 Feb 2021 18:27:19
Signature has been broken.	System	25 Feb 2021 18:27:19
User entered 'Yes (Y)'	System	25 Feb 2021 18:27:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User closed query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:49:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:49:22
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:14:05
Query 'Please confirm - per source no.' answered with 'correct' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 13:18:55
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	13 Nov 2020 13:15:30
User entered 'No (N)'	System	13 Nov 2020 13:15:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:04:21
User opened query 'Please confirm - per source no.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:54
Query 'Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:07
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:03:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'No (N)'	System	06 Nov 2020 16:48:27



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Yes (Y)'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Paul'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Bradley'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '340 Eisenhower Dr.'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'Savannah'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered 'GA'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:48:56
User entered '31406'	System	06 Nov 2020 16:48:27

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:04:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 15:03:28
User entered 'US'	System	06 Nov 2020 16:49:04



**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 14:46:35
User entered '7'	System	22 Mar 2021 15:40:20
User entered '6'	System	02 Mar 2021 15:13:17
User entered '5'	System	01 Mar 2021 14:57:35
Signature has been broken.	System	25 Feb 2021 18:28:48
User entered '4'	System	25 Feb 2021 18:28:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:44:56
	(b) (4)	
User entered '3'	System	16 Nov 2020 16:14:15
User entered '2'	System	11 Nov 2020 15:03:39
User entered '1'	System	06 Nov 2020 16:49:04

**US3022052**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000010**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 14:50:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:12:07
User entered '13/Apr/2021 10:46'	(b) (4) System	13 Apr 2021 14:46:35

US3022052

Folder: SAE USA-US051-2020-MRNA-1273-P301000010

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:50:47

**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)	13 Apr 2021 22:12:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:46:35